SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1965

No. 824

ABBOTT LABORATORIES, ET AL., PETITIONERS,

vs.

JOHN W. GARDNER, SECRETARY OF HEALTH, EDUCATION AND WELFARE, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

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[fol. A]

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Nos. 15054, 15055

ABBOTT LABORATORIES; ALCON LABORATORIES, INC.; ALLERGAN PHARMACEUTICALS; AMERICAN CYANAMID COMPANY; AMERICAN HOME PRODUCTS CORPORATION; AMES COMPANY, INC.; BARNES-HIND PHARMACEUTICALS, INC.; BAXTER LABORATORIES, INC.; BREWER & COMPANY, INC.; BURROUGHS WELLCOME & CO. (U. S. A.) INC.; CARTER PRODUCTS, INC.; CUTTER LABORATORIES; THE DOW CHEMICAL COMPANY; HOFFMANN-LA ROCHE INC.; HYNSON, WESTCOTT AND DUNNING INCORPORATED; JOHNSON & JOHNSON; ELI LILLY AND COMPANY; MALLINCKRODT CHEMICAL WORKS; THE S. E. MASSENGILL COMPANY; MEAD JOHNSON & COMPANY; MERCK & CO., INC.; THE NORWICH PHARMACAL COMPANY; OLIN MATHIESON CHEMICAL CORPORATION; ORGANON INC.; PARKE, DAVIS & COMPANY; CHAS. PFIZER & CO., INC.; PHILIPS ROXANE, INC.; A. H. ROBINS COMPANY, INCORPORATED; ROWELL LABORATORIES, INC.; SCHERING CORPORATION; G. D. SEARLE & CO.; SHERMAN LABORATORIES; SMITH KLINE & FRENCH LABORATORIES; STERLING DRUG INC.; WARNER-LAMBERT PHARMACEUTICAL COMPANY; PHARMACEUTICAL MANUFACTURERS ASSOCIATION,

v.

ANTHONY J. CELEBREZZE, Secretary of Health, Education and Welfare, and GEORGE P. LARRICK, Commissioner of Food and Drugs.

APPEAL FROM THE JUDGMENT OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

Joint Appendix—Filed October 28, 1964

[File endorsement omitted]

[fol. 1]

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

RELEVANT DOCKET ENTRIES

1.	9- 5-63	Complaint filed; Summons issued (exit papers to Marshal)..
2.	9- 5-63	Marshal returns on summons marked "Served 9-5-63".
3.	11- 5-63	Motion of defts to dismiss and for summary judgment, with Brief re same.
4.	11- 8-63	Cross Motion of Pltf for Summary Judgment.
5.	12-11-63	Memo of Pltf in support of Motion for Summary Judgment, and in opposition to deft's motion to dismiss & for summary judgment.
6.	1- 6-64	Reply Brief of Deft.
H.	1-13-64	Hearing Wright Ch. J. on cross-motions for summary judgment & deft motion to dismiss.
7.	1-15-64	Transcript of hearing Jan. 13, 1964.
8.	1-16-64	Reporter's notes of hearing on 1-13-64. 228 F. Supp. 855.
9.	4-30-64	Opinion Wright Ch. J.; Formal order to be submitted by counsel (Notice to counsel).
10.	5-15-64	Proposed form of judgment submitted by pltfs; June 10 Order Wright J. thereon.
11.	5-15-64	Proposed form of judgment submitted by defts.

[fol. 2]

	6-1-64	See Paper 10 for Judgment, Wright J. that pltfs American Home Products Corp., et al., Delaware corporations, and Pharmaceutical Manufacturers Association as representative of its member companies have standing to sue in this Court for the relief prayed in this action, and their Motion for Summary Judgment is granted; that Sections 1.104 (g)(1) and 1.105(b)(1) of the General Regulations, etc., issued by deft Commissioner of Food and Drugs, insofar as these sections require that the established name of a prescription drug must accompany each appearance of such drug's proprietary name or designation, are null and void and of no effect, and the statutory provisions on which they are based do not impose or authorize the defts to impose the requirements which they embody; enjoining defendants from enforcing, etc., said regulations; denying defendants' motion to dismiss and for summary judgment as to the plaintiffs named in paragraph (1) of the judgment; dismissing the complaint without prejudice as to the remaining plaintiffs for lack of proper venue, and that the respective parties shall bear their own costs of this action. (Notice to Counsel).
12.	7-29-64	Notice of appeal by certain pltfs.
13.	7-29-64	Bond of pltfs on appeal.
14.	7-29-64	Notice of appeal by defts (notice to clerk 3rd CCA and counsel).

[fol. 3]

IN THE UNITED STATES DISTRICT COURT

COMPLAINT FOR DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF—Filed September 5, 1963

Plaintiffs, for their complaint herein, allege:

1. This is an action for a declaratory judgment that certain regulations promulgated by defendants are unauthorized by and contrary to law, and for injunctive and other relief.

2. The action arises under the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040 (1938), as amended, 21 U. S. C. § 301, *et seq.* ("the Act"). This Court has jurisdiction pursuant to the provisions of 28 U. S. C. § 1331, 28 U. S. C. § 1337, 28 U. S. C. §§ 2201-02 and 5 U. S. C. § 1009. There exists between the parties an actual controversy, justiciable in character, in respect of which plaintiffs require a declaration of their rights by this Court. The amount in controversy between each plaintiff and the defendants exceeds $10,000, exclusive of interest and costs.

3. The plaintiffs herein are as follows:

Plaintiff	*State of Incorporation*	*Business Address*
Abbott Laboratories	Illinois	1400 Sheridan Road N. Chicago, Illinois
Alcon Laboratories, Inc.	Texas	6201 South Freeway Fort Worth, Texas
Allergan Pharmaceuticals	California	1000 S. Grand Avenue Santa Ana, California
American Cyanamid Company	Maine	859 Berdan Avenue Wayne, New Jersey
American Home Products Corporation	Delaware	685 Third Avenue New York, New York

Plaintiff	*State of Incorporation*	*Business Address*
Ames Company, Inc.	Indiana	819 McNaughton Avenue Elkhart, Indiana
Barnes-Hind Pharmaceuticals, Inc.	California	895 Kifer Road Sunnyvale, Calif.
Baxter Laboratories, Inc.	Delaware	6301 Lincoln Avenue Morton Grove, Ill.
[fol. 4]		
Brewer & Company, Inc.	Massachusetts	67 Union Street Worcester, Mass.
Burroughs Wellcome & Co. (U. S. A.), Inc.	New York	1 Scarsdale Road Tuckahoe, New York
Carter Products, Inc.	Maryland	2 Park Avenue New York, New York
Cutter Laboratories	Delaware	4th and Parker Streets Berkeley, California
The Dow Chemical Company	Delaware	1200 Madison Avenue Indianapolis, Ind.
Hoffman-LaRoche Inc.	New Jersey	340 Kingsland Street Nutley, New Jersey
Hynson, Westcott and Dunning Incorporated	Maryland	Charles & Chase Sts. Baltimore, Maryland
Johnson & Johnson	New Jersey	501 George Street New Brunswick, N. J.
Eli Lilly and Company	Indiana	740 South Alabama St, Indianapolis, Ind.
Mallinckrodt Chemical Works	Missouri	3600 N. Second St. St. Louis, Missouri
The S. E. Massengill Company	Tennessee	513-29 Fifth Street Bristol, Tennessee

Plaintiff	*State of Incorporation*	*Business Address*
Mead Johnson & Company	Indiana	2404 Pennsylvania Ave. Evansville, Indiana
Merck & Co., Inc.	New Jersey	126 East Lincoln Ave. Rahway, New Jersey
The Norwich Pharmacal Company	New York	17 Eaton Avenue Norwich, New York
Olin Mathieson Chemical Corporation	Virginia	745 Fifth Avenue New York, New York
Organon Inc.	New Jersey	375 Mt. Pleasant Ave. West Orange, N. J.
Parke, Davis & Company	Michigan	Jos. Campau at the River Detroit, Michigan
Chas. Pfizer & Co., Inc.	Delaware	235 East 42nd Street New York, New York
Philips Roxane, Inc.	Delaware	2400 Frederick Ave. St. Joseph, Missouri
A. H. Robins Company Incorporated	Virginia	1407 Cummings Drive Richmond, Virginia
Rowell Laboratories, Inc.	Minnesota	Baudette, Minnesota
[fol. 5]		
Schering Corporation	New Jersey	60 Orange Street Bloomfield, N. J.
G. D. Searle & Co.	Delaware	Searle Parkway Skokie, Illinois
Sherman Laboratories	(partnership)	5031 Grandy Avenue Detroit, Michigan
Smith Kline & French Laboratories	Pennsylvania	1500 Spring Garden St. Philadelphia, Penna.

Plaintiff	*State of Incorporation*	*Business Address*
Sterling Drug, Inc.	Delaware	1450 Broadway New York, New York
The Upjohn Company	Delaware	7000 Portage Road Kalamazoo, Michigan
Vale Chemical Company, Inc.	Delaware	1201 Liberty Street Allentown, Penna.
Warner-Lambert Pharmaceutical Company	Delaware	201 Tabor Road Morris Plains, N. J.
Pharmaceutical Manufacturers Association	Delaware (non-profit membership association)	1411 K Street, N. W. Washington, D. C.

The plaintiffs other than Pharmaceutical Manufacturers Association ("PMA") are hereinafter collectively referred to as "plaintiff companies."

4. Each of the plaintiff companies is engaged in the manufacture, and distribution in interstate commerce, of drugs, as that term is defined in Section 201(g) of the Act, 52 Stat. 1041 (1938), 21 U. S. C. § 321(g), and, more particularly, of drugs subject to the requirements of Section 503(b)(1) of the Act, 52 Stat. 1052 (1938), as amended, 21 U. S. C. § 353(b)(1), more commonly known as "prescription drugs."

5. PMA's membership includes about 140 member companies which are engaged in the manufacture of prescription drugs and which are believed to produce in excess of 90 per cent of the nation's total production of such drugs. The plaintiff companies are all members of PMA.

[fol. 6] 6. The defendant Anthony J. Celebrezze is the Secretary of the Department of Health, Education and Wel-

fare ("the Secretary"), who is charged with the administration of the Act. The defendant George P. Larrick is the Commissioner of Food and Drugs ("the Commissioner"), to whom the Secretary had delegated this authority. 22 Fed. Reg. 1051, as amended, 25 Fed. Reg. 8625. Each of the defendants is a resident of the District of Columbia.

7. The prescription drugs distributed by plaintiff companies in interstate commerce are not distributed directly to the patients who use these drugs. Rather, prescription drugs are distributed by plaintiff companies, or by their vendees, to physicians or other practitioners licensed by law (hereinafter "physicians"), to institutions, such as hospitals and clinics, in which the dispensing of prescription drugs is supervised by physicians, and to pharmacists, who in turn dispense those drugs to patients. No pharmacist or hospital or clinic may lawfully dispense prescription drugs to patients except upon the prescription or other direction of a physician. Accordingly, patients may lawfully obtain prescription drugs only from or pursuant to the direction of, and hence only under the supervision of, a physician.

8. In connection with its distribution of prescription drugs in interstate commerce each of the plaintiff companies prepares and distributes large quantities of labels, labeling material (such as product brochures) and advertising matter (such as advertisements in medical journals). Because, as set forth above, prescription drugs may be dispensed to patients only by or under the direction of a physician, labels, labeling and advertising matter for those drugs are not directed to the general public but rather to physicians, by plaintiff companies' professional service representatives, through the mails, in professional medical publications and the like, and, to some extent as in the case of material inserted in the drug's package, to the dispensing pharmacist, hospital or clinic. At all times each plain-
[fol. 7] tiff company has on hand and on order large quan-

tities of labels, other labeling material and advertising matter, prepared and printed at substantial expense, to be used in the future distribution of the prescription drugs which it manufactures.

9. The distribution by plaintiff companies of certain of the materials referred to in paragraph 8 is required by Federal law and regulations issued by the Commissioner and the distribution of the other materials there referred to is necessary or useful in the conduct of plaintiff companies' businesses.

10. There exists between the parties an actual controversy, justiciable in character, as to whether plaintiff companies may lawfully, without subjecting themselves to criminal prosecution, seizure and condemnation of their drugs, and injunctive actions, continue to distribute labels, other labeling material and advertising matter in which the established name, as defined below, of a prescription drug does not accompany every appearance of that drug's proprietary name, including labels, other labeling material and advertising matter printed and prepared at substantial expense and now in plaintiff companies' possession or subject to their control or now being ordered for subsequent distribution. The defendants, through formal and purportedly final and effective regulations, have taken the position that this material may not be distributed because it does not contain a statement of the established name of a prescription drug accompanying every appearance of that drug's proprietary name. Plaintiff companies believe that the defendants have no legal right to require such repetition of the established name and that such repetition will serve no useful purpose, will render the material less readable, and will impair the value of such material to plaintiff companies in the conduct of their businesses. The controversy turns upon the legal validity of these regulations, recently issued by the Commissioner, which regulations operate to prevent plaintiff companies from continuing their [fol. 8] present method of operating their businesses and to

interfere with mutually advantageous relationships which plaintiff companies have maintained with physicians and other persons. The genesis of said controversy is set forth below.

11. In accordance with conventional commercial practices and the trademark laws of the United States, proprietary, or brand, names are usually assigned by each plaintiff company to the prescription drugs which it distributes. The proprietary, or brand, name, which appears on the labels, and in the labeling and advertising, of the particular prescription drug, serves to identify the source of that drug. Said name serves the further function of distinguishing the drug from drugs with active ingredients of the same or similar chemical composition manufactured by other companies, including other plaintiff companies so that physicians may, if they wish to do so, when prescribing for patients, readily and conveniently express a preference among the sources from which such drugs are available by designating a drug by brand name. Since drugs with active ingredients of the same or similar chemical composition can and do differ in their therapeutic effect by reason of differences in binders and other inactive ingredients, and quality and methods of manufacture, the ability to distinguish between different brands of drugs with the same or similar active ingredients is important to physicians and to plaintiff companies in the conduct of their businesses.

12. Most prescription drugs can also be identified by a non-proprietary name. Such a non-proprietary name, often called "generic name," may be a "systematic chemical name," a "common or usual name," an "official title" used or adopted for use in an "official compendium" (United States Pharmacopeia, Homeopathic Pharmacopoeia, or National Formulary), or an "official name" designated by the Secretary under Section 508 of the Act, added by Section 111(a) of the Drug Amendments of 1962, 76 Stat. 789, 21 U. S. C. § 358. Under Section 502(e)(2) of the Act, added by Section 112(a) of the Drug Amendments of 1962, 76 Stat.

[fol. 9] 790, 21 U. S. C. § 352(e)(2), the term "established name" is defined as "(A) the applicable official name designated pursuant to Section 508, or (B), if there is no such name * * * the official title thereof in [an official] * * * compendium, or (C) if neither clause (A) nor clause (B) * * * applies, then the common or usual name * * * ." A single established name may be, and often is, the applicable established name for two or more prescription drugs distributed by different companies under different proprietary names.

13. Section 502(e)(1)(B) of the Act, 21 U. S. C. § 352(e)(1)(B), provides that the label and labeling of a prescription drug shall cause that drug to be "misbranded" unless:

> "The established name of such drug * * * on such label (and on any labeling on which a name for such drug * * * is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug * * * ."

14. Section 502(n) of the Act, added by Section 131(a) of the Drug Amendments of 1962, 76 Stat. 791, 21 U. S. C. § 352(n), provides that a prescription drug shall be deemed to be "misbranded" if the advertising for such drug does not contain:

> "A true statement of * * * the established name * * * printed prominently and in type at least half as large as that used for any trade or brand name thereof * * * ."

15. The introduction into interstate commerce of a "misbranded" drug and the "misbranding" of any drug in interstate commerce are declared unlawful by Sections 301(a) and (b) of the Act, 52 Stat. 1042 (1938), 21 U. S. C. §§ 331 (a) and (b). The introduction into interstate commerce of a prescription drug alleged to be misbranded or the alleged misbranding of a drug in interstate commerce may

result in the institution of (a) one or more seizure proceedings under which said drugs are sought to be condemned and forfeited, (b) an injunction proceeding, or (c) [fol. 10] criminal prosecution of the person or persons causing such introduction into interstate commerce. In a business such as that of the plaintiff companies, which depends heavily on the trust and confidence of physicians and the general public, the mere institution of any such action, regardless of its eventual outcome, can have serious financial and other consequences on the defendant thereto, since a large proportion of the general public and of physicians interpret the institution of any such action as reflecting adversely upon the effectiveness and purity of the drugs involved and the reputation of the manufacturer even if such action alleges no deficiency in the purity, safety, potency or effectiveness of the product. The consequences of a successful criminal prosecution or seizure proceeding are additionally severe in that such a criminal prosecution may result in a fine of $1,000.00 or a jail term of one year, or both, and such a seizure proceeding in the forfeiture of thousands of dollars worth of valuable drugs.

16. On February 14, 1963, the defendant Commissioner proposed the adoption of certain new general regulations under the Act. 28 Fed. Reg. 1448-49. With respect to prescription drugs, the proposed regulations required, *inter alia*, that on each label, and each piece of labeling and advertising, for a prescription drug bearing a proprietary name:

> "The established name, if such there be, corresponding to such proprietary name or designation, *shall* accompany *each* appearance of such proprietary name or designation. The established name *shall* appear in immediate conjunction with the proprietary name or designation, without intervening matter except the words 'brand of' or, alternatively, brackets surrounding the established name." (Emphasis supplied.)

17. Plaintiff companies believed that these proposed regulations were inconsistent with and went beyond the requirements of the statute, that the value of plaintiff com- [fol. 11] panies' labels, labeling and advertising would be impaired were this material to contain the statements to be required under the proposed regulations, and that the proposed regulations were in derogation of the basic statutory purpose. Plaintiff companies therefore individually or through PMA objected to the proposed requirement that the established name of a prescription drug accompany each mention of any proprietary or brand designation for that drug.

18. On June 20, 1963, the Commissioner promulgated final regulations. 28 Fed. Reg. 6375. These regulations recited that they were effective on publication. *Id.* at 6377. They contain in pertinent part a requirement that on the labels and in labeling and advertising of prescription drugs having an established name the established name not only must appear prominently and in letters at least half as large as the letters comprising the proprietary or brand name, but that also:

> "The established name, if such there be, corresponding to such proprietary name or designation, *shall* accompany *each* appearance of such proprietary name or designation. The established name *shall* be placed in direct conjunction with the proprietary name or designation, and the relationship between the proprietary name or designation and the established name *shall* be made clear by use of a phrase such as 'brand of,' preceding the established name, or by brackets surrounding the established name." Regulations, §§ 1.104(g)-(1), 1.105(b)(1). (Emphasis supplied.)

19. The regulations are written in mandatory terms and apply to all labels, labeling, and advertising used by plaintiff companies for their prescription drugs. Section 1.105(k) of the regulations provides that the issuance of a

drug advertisement not in compliance with Section 502(n) of the Act "and the applicable regulations thereunder shall cause stocks of such drugs in possession of the person [fol. 12] responsible for issuing or causing the issuance of the advertisement, and stocks of the drug distributed by such person and still in the channels of commerce, to be misbranded * * * ." The adoption and promulgation of the regulations impose a duty upon the defendants to enforce and to cause enforcement of the statute in accordance with the terms of such regulations.

20. These regulations are arbitrary and capricious and not in accordance with law, and constitute an unwarranted and unlawful directive to plaintiff companies in excess of the defendants' statutory authority and short of statutory right, and contrary to the statutory provisions on which they purport to be based. No provision of the Act requires, or authorizes the defendants to require, that a drug's established name accompany every appearance of that drug's proprietary name.

21. As heretofore recited, prescription drugs are dispensed to patients only under the supervision of physicians and accordingly the labels, labeling and advertising of prescription drugs are directed to physicians rather than patients. By virtue of their training and experience physicians are well aware that prescription drugs with active ingredients of comparable chemical composition are manufactured and distributed by different manufacturers, including different plaintiff companies, under different proprietary or brand names, and are well aware that the proprietary name of a prescription drug is a designation of its source and serves to differentiate that drug from drugs with active ingredients of the same or similar chemical composition distributed by other companies. So long as the established name of a prescription drug appears prominently on the label and in the labeling and advertising of that drug, and in type at least half as large as that used

for that drug's proprietary name, physicians are advised of the active ingredients of that drug and do not require repetition of the established name with each mention of [fol. 13] the proprietary name to realize the nature, type or composition of such drug.

22. In order that labels, labeling and advertising may perform their respective functions it is necessary that they be read by physicians. It is, therefore, of importance to physicians, their patients and plaintiff companies that the information contained on their labels, labeling and advertising be presented in an intelligible and readable manner. The aforesaid regulations, however, would cause labels, labeling and advertising to become confusing and repetitious and more difficult for physicians to read and understand than are plaintiff companies' present labels, labeling and advertising, while containing no more information than that contained in plaintiff companies' present labels, labeling and advertising.

23. As heretofore recited, prescription drugs having the same established name but different proprietary names can and do differ in their therapeutic effect. It is, therefore, fallacious to equate drugs with different proprietary names but the same established name, and the Congress had no intention of so doing. The regulations, however, by requiring a drug's established name to accompany in close conjunction every appearance of that drug's proprietary name, lead to the erroneous conclusion, detrimental to plaintiff companies' businesses and to patients, that drugs with the same established name are always and in all respects identical.

24. The effect of the aforesaid regulations, unless this Court enters a decree declaring that such regulations are unwarranted, unauthorized and unlawful, is to require plaintiff companies, in order to avoid criminal prosecution, seizure proceedings and injunctive actions, to cease the distribution of labels, other labeling material and adver-

tising matter (including boxes, brochures, mailing pieces, detailing pieces, file cards, bulletins, price lists, catalogues, house organs and print advertisements) in the same form [fol. 14] as heretofore distributed by plaintiff companies, including varying amounts of such materials now in their possession or subject to their control or on order. Some plaintiff companies are required by such regulations to revise and reprint at substantial expense such material now in their possession or subject to their control or on order, even though, as required by statute, the established name of the drug already appears on each document prominently and in type at least half as large as that used for any proprietary name. Further, the use of labels, other labeling material and advertising matter which comply with the regulations will impair the value to all plaintiff companies of these materials and injure plaintiff companies in their businesses.

25. Plaintiffs have exhausted all administrative remedies open to them, and have no prompt, adequate and effective remedy at law, and the present action is the only means available to them for the protection of their rights.

Wherefore, plaintiffs pray that this Court

(1) issue a judgment declaring that Sections 1.104-(g)(1) and 1.105(b)(1) of the General Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act, 28 Fed. Reg. 6375 (June 20, 1963), issued by the Commissioner purporting to act under authority delegated to him by the Secretary, are null and void and of no effect, and that the statutory provisions on which they purportedly are based do not impose, or authorize the defendants to impose, the requirements which they embody;

(2) enjoin and restrain the defendants and all persons acting under their direction and authority, or in active concert or participation with them, from enforcing or causing to be enforced, or from attempting to enforce or to

cause to be enforced, by any administrative action or civil or criminal proceeding, the requirements of such regulations; and,

[fol. 15] (3) grant such other or further relief as may be appropriate.

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[fol. 16]

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[fol. 17]

IN THE UNITED STATES DISTRICT COURT

MOTION TO DISMISS AND FOR SUMMARY JUDGMENT OF DISMISSAL—Filed November 5, 1963

I.

Come now the defendants, Anthony J. Celebrezze, Secretary of Health, Education, and Welfare, and George P. Larrick, Commissioner of Food and Drugs, and pursuant to Rule 12(b) of the Federal Rules of Civil Procedure, move

the Court to dismiss the complaint for declaratory judgment and injunctive relief filed herein for the following reasons and on the following grounds:

A. To dismiss the Pharmaceutical Manufacturers Association as a plaintiff as the Association lacks capacity to sue since there is no case or controversy between the Association and defendants.

B. To dismiss the following corporations as plaintiffs as the venue of this Court is improper, in that said plaintiff corporations are not residents of the State of Delaware as required by 28 U. S. C. 1391, and in that the Complaint affirmatively states that the firms are incorporated in States other than Delaware:

Abbott Laboratories—State of Illinois [Complaint, ¶ 3, p. 1]

Alcon Laboratories, Inc.—State of Texas [Complaint, ¶ 3, p. 1]

Allergan Pharmaceuticals—State of California [Complaint, ¶ 3, p. 1]

American Cyanamid Company—State of Maine [Complaint, ¶ 3, p. 1]

Ames Company, Inc.—State of Indiana [Complaint, ¶ 3, p. 1]

Barnes-Hind Pharmaceuticals, Inc.—State of California [Complaint, ¶ 3, p. 2]

[fol. 18] Brewer & Company, Inc.—Commonwealth of Massachusetts [Complaint, ¶ 3, p. 2]

Burroughs Wellcome & Co. (U. S. A.) Inc.—State of New York [Complaint, ¶ 3, p. 2]

Carter Products, Inc.—State of Maryland [Complaint, ¶ 3, p. 2]

Hoffman-LaRoche, Inc.—State of New Jersey [Complaint, ¶ 3, p. 2]

Hynson, Westcott and Dunning Incorporated—State of Maryland [Complaint, ¶ 3, p. 2]

Johnson & Johnson—State of New Jersey [Complaint, ¶ 3, p. 2]

Eli Lilly and Company—State of Indiana [Complaint, ¶ 3, p. 2]

Mallinckrodt Chemical Works—State of Missouri [Complaint, ¶ 3, p. 2]

The S. E. Massengill Company—State of Tennessee [Complaint, ¶ 3, p. 2]

Mead Johnson & Company—State of Indiana [Complaint, ¶ 3, p. 2]

Merck & Co., Inc.—State of New Jersey [Complaint, ¶ 3, p. 2]

The Norwich Pharmacal Company—State of New York [Complaint, ¶ 3, p. 2]

Olin Mathieson Chemical Corporation—Commonwealth of Virginia [Complaint, ¶ 3, p. 2]

Organon Inc.—State of New Jersey [Complaint, ¶ 3, p. 2]

Parke, Davis & Company—State of Michigan [Complaint, ¶ 3, p. 2]

A. H. Robins Company, Incorporated—Commonwealth of Virginia [Complaint, ¶ 3, p. 3]

[fol. 19] Rowell Laboratories, Inc.—State of Minnesota [Complaint, ¶ 3, p. 3]

Schering Corporation—State of New Jersey [Complaint, ¶ 3, p. 3]

Sherman Laboratories—partnership—business address: Detroit, Michigan [Complaint, ¶ 3, p. 3]

Smith Kline & French Laboratories—Commonwealth of Pennsylvania [Complaint, ¶ 3, p. 3]

C. To dismiss the action in its entirety as this Court is without jurisdiction to entertain this suit because the

complaint fails to allege a case of actual controversy within the meaning of the Declaratory Judgments Act.

D. To dismiss the action in its entirety as the complaint fails to join an indispensable party, the Attorney General of the United States.

E. To dismiss the action in its entirety as the complaint fails to allege sufficient facts to state a claim appropriate for the exercise of the Court's discretion under the Declaratory Judgments Act. A regulation which interprets a portion of the Federal Food, Drug, and Cosmetic Act is not sufficient to support a suit for a Declaratory Judgment. Further, plaintiffs have not alleged facts which indicate that there has been any threat of enforcement with respect to plaintiffs.

F. The Court is without jurisdiction to entertain this suit because it is in substance and effect a suit against the United States to which it has not consented.

II.

The defendants further move the Court, pursuant to Rule 56 of the Federal Rules of Civil Procedure, to grant summary judgment of dismissal in favor of the defendants on the grounds that there is no genuine issue as to any material fact which precludes relief to the defendants, and [fol. 20] that defendants are entitled to judgment as a matter of law, since the regulations in question are reasonable, are in accordance with the clearly expressed intention of the Congress, and carry out the purpose of the statute.

Respectfully submitted,

Alexander Greenfeld, United States Attorney, Wilmington, Delaware.

William W. Goodrich, Assistant General Counsel for Food and Drugs.

Joanne S. Sisk, Nancy N. Keefe, Attorneys, United States Department of Health, Education and Welfare, Washington, D. C. 20201.

[fol. 21]

IN THE UNITED STATES DISTRICT COURT

PLAINTIFFS' CROSS-MOTION FOR SUMMARY JUDGMENT—
Filed November 8, 1963

Each of the plaintiffs separately opposes both defendants' motion to dismiss and defendants' motion for summary judgment and cross-moves the Court on the papers filed in this proceeding for summary judgment under Rule 56 of the Federal Rules of Civil Procedure on the ground that there is no genuine issue as to any material fact and that plaintiffs are entitled to judgment as a matter of law.

Alexander L. Nichols, William S. Megonigal, Jr., 3000 DuPont Building, Wilmington 1, Delaware, Attorneys for Plaintiffs.

Of Counsel:

Morris, Nichols, Arsht & Tunnell, 3000 DuPont Building, Wilmington 1, Delaware.

Gerhard A. Gesell, Stanley L. Temko, Herbert Dym, 701 Union Trust Building, Washington 5, D. C., Attorneys for Abbott Laboratories; Alcon Laboratories, Inc.; Allergan Pharmaceuticals; American Cyanamid Company; American Home Products Corporation; Ames Company, Inc.; Barnes-Hind Pharmaceuticals, Inc.; Baxter Laboratories, Inc.; Brewer & Company, Inc.; Burroughs Wellcome & Co. (U. S. A.) Inc.; Carter Products, Inc.; Cutter Laboratories; The Dow Chemical Company; Hoffman-LaRoche Inc.; Hynson, Wescott and Dunning, Incorporated; Johnson & Johnson; Eli Lilly and Company; Mallinckrodt Chemical Works; The S. E. Massengill Company; Mead Johnson & Company; The Norwich Pharmacal Company; Olin Mathieson Chemical Corporation; Organon Inc.; Parke, Davis & Company; Chas. Pfizer & Co., Inc.; Philips Roxane, Inc.; A. H. Robins Company, In-

corporated; Rowell Laboratories, Inc.; Schering Corporation; G. D. Searle & Co.; Sherman Laboratories; Smith Kline & French Laboratories; Sterling Drug, Inc.; The Upjohn Company; Vale Chemical Company, Inc.; Warner-Lambert Pharmaceutical Company.

Of Counsel:

Covington & Burling, 701 Union Trust Bldg., Washington 5, D. C.

[fol. 22] Hayward H. Coburn, 1100 Philadelphia National Bank Building, Broad and Chestnut Streets, Philadelphia 7, Pennsylvania, Attorney for Merck & Co., Inc.

Of Counsel:

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Lloyd N. Cutler, Marshall Hornblower, 815—17th Street, N. W., Washington 6, D. C.; C. Joseph Stetler, Vice President and General Counsel, John K. Worley, Assistant General Counsel, Pharmaceutical Manufacturers Association, 1411 K Street, N. W., Washington 5, D. C., Attorneys for Pharmaceutical Manufacturers Association.

Of Counsel:

Wilmer, Cutler & Pickering, 815—17th Street, N. W., Washington 6, D. C.

November 8, 1963.

[fol. 23]

IN THE UNITED STATES DISTRICT COURT

Excerpts From the Transcript of the Oral Argument —January 13, 1964

Wilmington, Delaware

Before: Hon. Caleb M. Wright, Chief Judge.

APPEARANCES

For the Plaintiffs:

Alexander L. Nichols, Esq., and William S. Megonigal, Jr., Esq., of Morris, Nichols, Arsht & Tunnell;

Gerhard A. Gesell, Esq., Stanley L. Temko, Esq., and Herbert Dym, Esq., of Covington & Burling, Washington, D. C.;

Hayward H. Coburn, Esq., of Drinker, Biddle & Reath, of Philadelphia, Pa.;

Lloyd N. Cutler, Esq., and Marshall Hornblower, Esq., of Wilmer, Cutler & Pickering, of Washington, D. C.;

John K. Worley, Esq., of Washington, D. C.

For the Defendants:

Alexander Greenfeld, Esq., U. S. Attorney, and William J. Wier, Esq., Asst. U. S. Attorney;

William W. Goodrich, Esq., Asst. General Counsel for Food and Drugs.

COLLOQUY BETWEEN COURT AND COUNSEL

Mr. Goodrich: • • • If these procedural matters are not adequate to dismiss, then, of course, we defend the [fol. 24] regulations on their merits and contend that they are plainly authorized by the law to carry out the evident intent of the Congress and should be sustained.

• • • • • • •

The Court: Mr. Goodrich, when your department makes a regulation, I certainly hope that you intend for the drug industry to obey those regulations.

Mr. Goodrich: We do indeed, sir.

The Court: If not, you take whatever steps are necessary to enforce them.

Mr. Goodrich: But the enforcement in the setting of a real case, where we have a piece of promotional material before us, is entirely different from an abstract question which is presented here.

• • • • • • •

We have here a case in which the Congress' attention has been sharply focused on this very issue and it has settled it. Under the gambling device case from Justice Jackson, which we have cited in our brief, this is entitled to a very strong presumption.

The Court: Let me get this straight now. The sharp focus which you are referring to is based upon two things, is it not: The rejection of the O'Brien amendment and the statement of Senator Kefauver when he was making the report of the joint—

Mr. Goodrich: I go back also, your Honor, to the first Senate report in August. There was a July report of the [fol. 25] first Senate bill. Then the second report after the President's call for strengthening of the bill originally reported out by Senator Eastland's group.

The Court: What is there in the first Senate report?

Mr. Goodrich: "Wherever". The same language that wherever the trade name is used the generic name should be used.

The Court: That is what we are trying to do, to figure out what the "wherever" means.

Mr. Goodrich: Yes, sir.

The Court: And the only place we can find that—I mean you have to base it upon the failure to adopt the O'Brien amendment and the statement of Senator Kefauver in making the report; isn't that true?

Mr. Goodrich: I think the other report is very significant, because it uses the same language that Senator Kefauver later used to explain what was meant by "wherever".

The Court: Is there anything in the report where it says, "We intend that every time the brand name is used the generic or established name shall follow"?

Mr. Goodrich: Only the word "wherever". "Wherever" is explained—the statutory language is in it and the word used in the first report on S-1152, part 2, is that "any" means "wherever", and this was then cut back by the O'Brien amendment, and then went to conference, and Senator Kefauver came back with the identical language that was in the original S-1152 that was reported out in August, [fol. 26] and this is the contention that we have on the legislative history.

The Court: Go ahead. Don't let me stop you.

Mr. Goodrich: I have concluded. I thought you might have another question, your Honor.

The Court: I was trying to find this.

Mr. Goodrich: You will find this on page 8 of the second part of the Senate report 1744. Here is the language: "It would also require that on the labels and any labeling, wherever a trade or brand name is used, the established name as defined in this section must be shown in type at least half as large as that used for any trade or brand name." This part of the report, your Honor, follows the bill and is in the debate in the Senate right at the first part of the compilation. Thank you, your Honor.

The Court: Thank you.

Mr. Gesell: If the Court please, I think the best starting point is to start at the point where Mr. Goodrich started. This is not a question of trying to win in a courtroom something that was lost in the Congress any more than it is a question of the FDA trying to prevail in a court on an issue that they would have liked to have seen Congress decide in their favor in the legislative history. I think it is not helpful to present this case except in these terms: A major

industrial problem of transcendant consequence cutting across all of the companies is presented here, and we are not trying to tell the agency how to administer the Act, as Mr. Goodrich suggests. We are asking your Honor to tell them that they cannot exceed the authority that was given them by the Congress. They can administer the Act any way they please within the authority that they have, but they cannot exceed that authority.

The specific issue here is whether they are not exceeding that authority in saying that we must on every adver- [fol. 27] tisement of a prescription drug, on every label and every price list and every box, every mailing piece, every carton, every bit of literature that we have, every time we use our trade name also present the information as to the generic name. We say Congress did not require that; that the statute does not direct them to do that; that their command is a command beyond the scope of the statute; and that they are acting illegally; and we have come here as an industry to get that issue resolved. We are not asking in any way for an abstract opinion. We are asking to be relieved of the burden of an unauthorized action by the agency in the administration of the statute, and that is our right, as I intend to show.

The impact of this regulation is a very real one. It affects the manner in which all of these companies must order their affairs. It affects a multitude—I don't know whether one could estimate it, but certainly in the hundreds of thousands of different pieces of literature that are printed and reprinted daily. It affects thousands of drugs, and this industry is entitled and these plaintiffs I represent are entitled to have that determined. This is not as though Mr. Goodrich had made some kind of a speech to some kind of group of drug people or answered some kind of a casual letter, both of which he does quite frequently. This is entitled "A Regulation for the Enforcement of the Act." It is published in the Federal Register and it tells each of my clients and all the other drug companies that what they are doing is illegal; that their drugs can be seized and kept off

the market because they are doing it; that their officers can go to jail because the companies are doing it; that we are subject to injunction; and, as Mr. Goodrich says, that we stand and confront the possibility of the administrative operation by the agency itself not only in its referrals to the Attorney General, but in its handling of new drug applications. We are confronted with something very real.

[fol. 28] The Court: Would you call it "jeopardy"?

Mr. Gesell: I think the words that the cases use are "at peril" or "at risk". "Jeopardy" would be equally good. We are, and we are daily in it, and it seems to me that the impact of this regulation is obviously immediate and obviously real, and to get the flavor from the brief and, I must say, from the argument today that all they have done is to try to help us out by giving us a little old interpretation, and that maybe sometime in connection with some drug somewhere at their own choosing, their own forum, their own place, their own opportunity, they might bring a case, criminal, civil, or what not, is to understate what has happened. Surely they mean this regulation. Surely when they put it out and say this is what you shall do—not what you could do to live up to the statute, not what we think would be best for you to do, not one possibility, but you shall do it, and they put it out as an enforcement regulation, we have got a practical problem as businessmen that we have to get some relief on. Now, if the statute is held to mean what Mr. Goodrich says, these companies will comply with it. But they should not be required to comply with a directive of this character which is beyond the authority that they have from the statute.

In the main that is why we are here. We think the risks are immediate. We think they are very real. The agency is going to enforce this statute obviously in the manner they say, and we feel that we are entitled to come here for relief.

* * * * * * *

Now, on the question of the merits, if your Honor please, I think we ought to have the provision in front of us. It is at 3a, printed in the appendix of our brief.

Now, the Food & Drug Administration says that this section requires this regulation, that they have no choice, [fol. 29] that this says to them, it must be every time. They are explicit on that at page 33 of their brief. And I would simply say that a reading of it just in the normal manner that anyone would read it can't possibly pull from it that meaning. The ambiguity that he seeks to create in order to psychoanalyze these different Congressmen just isn't there. This is a straightforward statement of what Congress said, and it is just as clear. It says that you must print the generic name prominently and you must print it in type at least half as large. But it doesn't say "every time".

We are not dealing, your Honor, with a very abstruse concept. I think Congressmen would understand that if they meant every time, they could say "every time", And if they had said "every time", I call your Honor's attention to the fact that they would not have needed to say "prominently" at all. They have specified that the type must be half the size. What is the point of "prominently" in the statute if it was an "every time" statute? This simply directs clearly that you must print the generic name. It gives the size of type, and they say it must be prominent. But it does not say in its four corners in any way "every time".

We don't see the ambiguity that necessitates the legislative hunt, which I am going to go through with you and give you our view on phases of it. For an officer of the Government to stand up and say that that is a direction to him to require every label and, on the related provision of the next page, every ad to show this "every time" is to assume that the Congressmen didn't use the simplest, most ordinary and most natural English to express the simplest, most ordinary idea.

We are not concerned with some abstruse field of law. We are not concerned with possible misunderstandings [fol. 30] about the intricacies in the Congress. I cannot con-

ceive of any Congressman not saying, "Well, if it is to be every time, why don't we say so?" And how could this bill, kicked around back and forth as it was, up and down, both houses of Congress how could it be that nobody said, "Why, look, if we mean 'every time', let's just put it in"? It seems to me that is not the idea of a statesman; that is the idea of anybody who normally is in the legislative function; and the fact that it did not happen and that rested purely on prominence as opposed to "every time" in my judgment is clear from the face of the language itself.

Then Mr. O'Brien came along and he said, Well, I think I have a resolution for it. Let's make them do it the first time.

And they said, No, we don't like that idea. We think it is preferable to remain where it was in terms of prominence.

We have cited, your Honor, the specific language of the Managers, which I think appears at page 13 of our brief—

The Court: Mr. Gesell, before we get into the legislative history of this, may I digress a minute here.

I have listened to what you had to say on this particular section which is at issue, which is 502(e), I believe.

Mr. Gesell: They are both at issue, 502(e) and (n).

The Court: What is your interpretation of 502(n) with reference to the advertisement?

Mr. Gesell: It is the same.

The Court: In other words, that it is not required in the advertising?

Mr. Gesell: No. That is right.

[fol. 31] The Court: Or in the literature; for the established name to be prescribed but once and then half the size?

Mr. Gesell: I do not say but once, your Honor; I do not say but once. I say that the statute says—

The Court: It doesn't have to do it every time, doesn't have to be printed. All right.

Mr. Gesell: Every time. It must just be prominent. Mr. Goodrich says I say once, but I do not. It is up to this

agency to deal with the problem of prominence, but to say "every time" and to say that the statute requires the "every time" is where I believe they have exceeded their authority.

The Court: Well, under your argument where is there any authority for them to make a rule or regulation more than once?

Mr. Gesell: Well, I would suppose that under the rule-making power that they have, if they felt they wanted to give more meaning to a word, to the word "prominent", that they would be able to do that, as I think they have where that word has appeared in other sections of the Act.

The Court: You mean that if they did that, then that would be reasonable, but what they are doing here is unreasonable?

Mr. Gesell: No, no. But, see, then they would have to go through a rule-making process that they could support with logic and with findings and with facts under the Administrative Procedure Act. They have not done any of that. I don't say that one time is sufficient. It probably would be on many things. I would certainly think so on most one-page things and on most labels. Perhaps an issue would arise that if you got a book—

[fol. 32] The Court: Well, I could think of writing a paper four or five pages long and using it just once and never using the brand name again. If seems to me that if the drug people wanted to do that, that they confuse the doctor more than ever.

Mr. Gesell: Well, yes, because as they fell away from the brand name, then the doctor doesn't know what is involved. The suggestion that this trained group of people—and we are talking of prescription drugs, and the advertising, you realize, is in medical journals—has to have it every time in order to understand it, is like my saying to your Honor, or having some court say to both of us that in a brief like this every time I say "plaintiffs and defendants" I have to put a paren and list all these plaintiffs and de-

fendants each time so you are sure you know what I am talking about.

The Court: I might not read your brief.

Mr. Gesell: I think you might not. And I think the doctor may not read that. And of course, your Honor, we made specific allegations of that character which are not controverted here. There is no answer, there is no answering affidavit, that this was confusing, that it tended to detract from the individuality of the products, and all of those issues are here. But it is perfectly clear to me that Congress could not have had this concept in mind and not have said so.

Now, that is a simple statement, but I think that is the issue here. Could anyone have meant—a responsible group of men—we will assume they all had a high school education or better—could they have written a statute to mean "every time" and never said it?

[fol. 33] Now, I find it incredible to believe that the interpretation which is proposed here is what was intended, just as in our own practical knowledge and common sense—

. . . . . .

It means to me that you must look and give great weight to the statute. You then must give weight to the formal documents in terms of order, and it is only as you get way down this scale of legislative history as to what the Supreme Court Judges have said as to psychoanalyzing Congress that you are put into the question of trying to understand what Senator Kefauver meant in the statements to which we refer.

The Court: Well, don't you feel that what Senator Kefauver said was pretty obvious when he made his report?

Mr. Gesell: Yes, I think it is pretty obvious.

The Court: What the Senator had in mind.

Mr. Gesell: If we are talking about the same statement.

The Court: I am talking about the statement on page 20870, Section 112.

Mr. Gesell: Let me get that, your Honor. Yes, you are talking about the statement—

The Court: It is in your brief, too.

Mr. Gesell: Yes, at the top of page 12. Is that the one we are talking about?

The Court: I think so, yes. Let me just check this. Well, yes, but that does not state the whole thing. Let me read it for the record. It says in this section—this is Senator Kefauver speaking—Section 112: "Name to be used on drug labeling":

> [fol. 34] "In this section both the Senate and House versions were identical with one exception. This was a limitation upon the frequency with which the established name should appear in labeling, which among other things includes direct mail advertisements, brochures, pamphlets, and so forth; under the limitation the established name would have had to be printed only 'at the first place, and at the most conspicuous place if other than the first place, at which such proprietary name for such drug or ingredient, as the case may be, is used.'"

Now, that is the O'Brien amendment he is talking about.

Mr. Gesell: Yes.

The Court: "This limitation was not accepted by the conferees. Thus the established name of a prescription drug must appear in type at least half as large as the trade name wherever the latter is used in drug promotional matter, including package inserts, and so forth."

Mr. Gesell: Now, I didn't hear the words "every time".

The Court: Well, what am I reading here?

Mr. Gesell: I think you are reading the same thing I am reading. That is the closest you come and it has got the word "wherever" in it.

The Court: Well, all right. I am glad I read that over.

Mr. Gesell: And it is just what Mr. Eastland said when he said "if".

The Court: I think Mr. Goodrich brainwashed me pretty well because when I read that up here to myself I read into it "every time". I thought that is what Senator Kefauver had said. So I am glad I read that out loud.

[fol. 35] Mr. Gesell: I had not thought that he ever had said "every time". That is why I asked which statement you were referring to.

The Court: I looked through this rather hurriedly to see if anybody had ever said anything about "every time", and I didn't think it did until this morning when I read that and I was trying to listen to your argument, and I read "every time" into Senator Kefauver's words.

* * * * * * *

The Court: I don't know that we could go that far. I think that we would have to rely upon your expertise in this maybe to every piece of labeling that came along unless it was something that was practically—I mean, that everybody looked at and said, "Why, this is ridiculous."

Mr. Goodrich: But you would have the setting of a real case, your Honor, my point is, rather than here you are passing on—Mr. Gesell finally agrees with me—a multitude of promotional pieces that you have not seen. You are being asked to rule that we cannot require the "each time" without seeing how it might work, without seeing how the firms actually tried to comply, and if they did not comply, then there is no question of anybody going to jail or anything being seized, if we are wrong in our interpretation. But this is where these cases have been set for approval and for review.

Now, I think I must get to your other point of nobody ever saying "every time". Senator Kefauver said—

The Court: Let's get back to this final action business. I am not sure that you have answered me.

Mr. Goodrich: The regulation is a final interpretive regulation. It only becames a final operative regulation under the cases which we have cited when it is applied to a specific fact situation in an enforcement case.

[fol. 36] The Court: But isn't this final in the sense that nothing remains to be done except somebody disobey this and you make a recommendation to the Department of Justice to prosecute?

Mr. Goodrich: On a particular fact setting, yes, but the particular fact setting has to arise first. This is just like the Los Angeles case we cited—

The Court: Do you mean to say that in any case of controversy there always has to be a single action between civil plaintiffs and someone?

Mr. Goodrich: There has to be a concrete factual issue so that your judgment may take effect and be a final judgment as a matter of res judicata, settling rights between the parties, not just coming out with an advisory opinion on what the statute means in the abstract. This is my problem, that you are asked to come out with an interpretation of the statute which will be binding on us as an agency of the United States, binding on the Attorney General presumably if he ever wants to come out with an enforcement action.

The Court: Only insofar as if I were to say that you had exceeded the authority under the statute. If I do that, it leaves it to you to determine what new regulation you want to make.

Mr. Goodrich: I am glad you mentioned that.

The Court: Maybe you might be back in this same Court, or maybe if I did that, you would try to arrange some method to get out of this District and someplace else.

Mr. Goodrich: I am the defendant here, your Honor.

The Court: I know, but you might try.

[fol. 37] Mr. Goodrich: If it weren't for the honor of the thing, I would just as soon not be here, as Will Rogers once said.

The point I am making is there isn't any middle ground here.

You asked a very excellent question of Mr. Gesell and he answered it by referring to a non-existent statutory procedure. Where do we go from the "one time" to the "each time"? Where do we get the statutory authority to say it goes on each page or it goes on every fourth page or it goes at the top or it goes at the bottom? We considered all those things. We tried to arrive at what we thought the Con-

gress had in mind and when they said "wherever" we thought they meant everywhere. This is the normal meaning of the language used.

The Court: You don't mean to tell me that you looked at this statute as Mr. Gesell looked at it and said "This is too hard to say just where we should stop, so we will just make it every time."

Mr. Goodrich: No, we did not, your Honor. We went to actually what Congress had done. We tried to be true to the job we have in the executive branch to carry out what Congress said. Now, Congress took this very point up. It was not any problem of psychoanalysis. As I understand psychoanalysis, you are searching for some subconscious feeling that the patient does not know he has and you are trying to explain why he is sick on that basis. We don't have to look for subconscious expressions here or get a couch or any other thing. We simply have to look to what the Congress did in rejecting the amendment of Mr. O'Brien; what Senator Kefauver, speaking for the Senate conferees, said to the world. The conference committee was a closed meeting. He is the only one that explained exactly what happened there. Senator Kefauver is the father of this bill. You read this legislative history all the [fol. 38] way through and you come out with the feeling that everyone, including Senator Eastland, deferred to his understanding of what had happened in the conference report, and there we are. If you rule that we can't do it every time we would hope that you would tell us how to do it, and this is where our trouble is.

The Court: I can't do that.

Mr. Goodrich: What kind of judgment are we going to have then? If you are going to give us some legal advice we would appreciate that, but we don't think it can be a binding judgment.

The Court: I don't want to give you an advisory opinion.

Mr. Goodrich: Sir?

The Court: I don't want to give you an advisory opinion.

Mr. Goodrich: Well, if you rule against "every time"—we hope you will—we are going to have to know what the

thinking is that tells us that there is something in this statute between "one time" and "every time".

To get back to the prominence of the thing, the problem of the prominence was to be sure it was not sunk over in very small print. Some of these promotional pieces use newspaper-type print, which is eight point. Half the size would be four point and you would have to have your trifocals in order to see it, and the statute says prominently, but in type at least half as large.

When I go to the business of the declaratory judgment always authorizing this sort of an action, there aren't any cases on the books that tell us that. Mr. Gesell says that Larson is the authority. Larson is directly in our favor. [fol. 39] I request your Honor to read Adams and Nagle in it, which covers the very point he made.

On Storer, if I may be permitted—I know our time is getting late—

The Court: That is all right. You keep right on. I am asking you these questions and I have asked Mr. Gesell these questions in order to elicit all the aid I can.

Mr. Goodrich: I have argued enough cases, your Honor, to know that I get more good out of an argument when you ask me a question than if I talk all day, because this is the only way we can really communicate. So I appreciate the questions.

From Storer, however, there is a quote which says, "If the respondent could not rightfully seek a review from the order adopting the challenged regulations it must await action to its disadvantage under them. In the light of the legislation allowing review we hold that he has standing."

That is my point about those cases. There was a special provision in the Communications Act which authorized a suit before a three-judge court to enjoin the enforcement of regulations. This is now part of the Hobbs Act. I am sure you are familiar with it. There is nothing of that kind here. Where Congress provided review before the Court of Appeals they said so. They said so in this very statute under 502(n). This is the one on the advertising.

They allowed review of the regulations we established telling what would be in the advertisement in terms of effectiveness, side effects, and so forth. They did not make it applicable to this type of regulation. Nothing could show a stronger intention of the Congress.

When we took the Ewing v. Mytinger and Casselbury case to the Supreme Court the Court held that Congress [fol. 40] had done a selective job here of making some provisions reviewable and making others not reviewable.

They cited the Brotherhood case, which Congress precluded review by not providing for it in one place and by providing for it in another. This is cited in the Ewing v. Mytinger and Casselbury case

The main problem I do think that I must turn to is this point that Mr. Gesell makes so strongly and apparently impressed you that no one ever said "every time". If somebody meant it why didn't they say it? We take the position Kefauver said it not once, but said it in the committee report in August, said it again after Mr. O'Brien had tried to cut it back, and that we are simply faced with a practical problem here of how to administer this statute. If we don't go to "every time", Mr. Gesell's brief doesn't help us. He says that he does not mean only once. If you read his brief it says once on page 6, and when you get on over a little later he says that the limited presentation in the O'Brien amendment was not necessarily adequate. Now, where is the middle ground? We think that the Congress with its eyes wide open required every time. There is nothing wrong with every time.

You mentioned the situation of a medical article which might use the brand name only once. This is the usual situation in the papers in the American Medical Association Journals, for example. They are required to use the established name in discussing the drug, and the trade name might be in a footnote. Congress here did not want to do away with the trade name, but they provided that the established name should be used every time so that doctors could be educated to equivalency. We think that is what the statute means.

Thank you. Do you have any further questions?

[fol. 41] The Court: No, I think that is all. If I may I would like to ask Mr. Gesell one question.

Mr. Gesell: Yes, your Honor.

The Court: I must say, Mr. Gesell, when you got away from the use of the name once I was a little bit surprised. Just as a practical matter, have you got any idea how the Department could administer this Act if it does not mean just once or every time?

Mr. Gesell: Yes, your Honor, and what I would like to do is, if I may, say this: That I have not explored this matter with all of my clients and I am speaking purely personally now and I don't know the view of all these different companies. But it is perfectly apparent to me that there is a middle ground. I think Mr. Goodrich is asking you to give him the advisory opinion, not I.

The Court: I don't have the authority, but I thought from the argument you might be able to give it to me.

Mr. Gesell: Well, one can conceive of coming at it in terms of having to be once on every page of multi-page documents. One can come with the view that if the trade name were used in the title of some kind of publication this should also be in the title. There are ways short of every time. You have no idea what this does to a piece of literature. It is just as though—I do not mean to be sacrilegious, your Honor—one read the Bible and one always defined who the Lord was every time the Lord's name appears in the document. It absolutely will drive physicians, companies, readers, and everyone else to distraction. There are certain ways that intelligent people could work it out. We have indicated to Mr. Goodrich a willingness to sit down and try to work it out with him, but we are not going to take lying down the notion that we have to do it his way when Congress didn't tell him that.

[fol. 42] The Court: Do you mind if I let Mr. Goodrich answer you?

Mr. Gesell: No, no, your Honor.

Mr. Goodrich: I must simply say, your Honor, that in order for you to pass on the validity of what Mr. Gesell

has just said here you will have to look at the promotional pieces. This is why we think it is so essential that the application of this regulation await the actual presentation of promotional pieces.

Now, I had a group of them organized to bring here. Mr. Gesell's people did not particularly want to present it at this time. I deferred and presented the case on this basis, but I cannot emphasize too strongly that the actual operation of this statute cannot be passed on in the abstract by any such idea that it will ruin the promotional piece to use the generic name.

The Court: Sir, you don't have the manpower, do you, to go over every piece of promotional literature? There has got to be some way that some rules and regulations which are apparent to you and also reasonably clear to the industry without—

Mr. Goodrich: We think our regulations are clear.

The Court: There is no question about your regulation now that it is perfectly clear, but there has got to be some clarification of this thing. I don't think I have to get into the practicality of this matter, but, nevertheless, I always like to know the practical side of it. But I don't think that this Court has to look at every piece of literature any more than you do to determine whether or not this statute and what you have done is beyond the authority given you by the statute. All I am saying is you just like to know what the practical effect is going to be.

[fol. 43] Mr. Gesell: May I point out, your Honor, in this informal discussion, that this enforcement regulation runs equally to every type of piece of paper across the board. Mr. Goodrich is talking about looking at these pieces of paper. His enforcement regulation treats of everything identically.

Mr. Goodrich: We do recall from the establishment of "each time" we think that is what Congress required. We think the reviewability of that type regulation does not apply in this sort of suit for declaratory judgment.

[fol. 44]

IN THE UNITED STATES DISTRICT COURT

OPINION—April 30, 1964

WRIGHT, *Chief Judge.*

This action arises under the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, as amended, 21 U. S. C. § 301, et seq. ("the Act").

According to § 502(e)(1)(B) of the Act, 21 U. S. C. § 352(e)(1)(B), the labeling of a prescription drug shall cause that drug to be "misbranded" unless the established or generic name of the drug is printed prominently on any label or labeling material, as defined in the Act, in type half as large as any brand or proprietary name.[1]

The proprietary, or brand name, of a prescription drug is used by the manufacturer to identify the source of the drug. The proprietary name distinguishes the drug manufactured by one company from the drug with active ingredients of the same or similar chemical constitution produced by another company. Thus a physician can, if he desires, exercise a choice among sources in prescribing drugs for his patient.

Most prescription drugs also have a non-proprietary or generic name. Such a name may be a systematic chemical name, a common name, or an official name used in some official compendium or designated by the Secretary of Health, Education and Welfare. This is the "established name" which § 502(e)(1)(B) requires to be prominently displayed on drug labeling. If this requirement is not met and a misbranded drug is introduced into interstate commerce (a) the drugs may be seized and forfeited, (b) the introduction of such drugs into interstate commerce may be enjoined, (c) the persons who cause introduction of the

[1] The language of § 502(n) of the Act, 21 U. S. C. § 352(n) which applies to advertising is similar. This opinion covers both sections although only § 502(e) is specifically discussed.

misbranded drugs into interstate commerce may be subject to criminal prosecution.

[fol. 45] In February, 1963, the defendant, Commissioner of Food and Drugs proposed the adoption of certain new regulations under the Act. The final regulations, 28 Fed. Reg. 6375, were promulgated in June, 1963 and were effective on publication. It is these regulations which are under attack in the present proceeding. Under the new regulations the Act is interpreted to require that the established or generic name be placed in conjunction with every appearance of the proprietary name of the drug on labels and advertising.

Thirty-seven drug companies and the Pharmaceutical Manufacturers Association (PMA) have joined as plaintiffs to challenge the every time requirement. They claim that the statute does not direct or authorize the defendant Commissioner to impose the requirement and that the Commissioner's regulations are therefore null and void. They seek a declaratory judgment to that effect and an injunction restraining defendants from enforcing the disputed regulation. The plaintiffs assert that in the absence of such relief they will be forced to choose between flouting the regulation and possibly incurring penalties or reprinting great quantities of advertising material which already complies with the statute as plaintiffs interpret it. This material, including brochures, price lists, catalogues and labels prominently sets forth the generic name of the prescription drug involved but it does not meet the every time requirement.

At the outset, a host of jurisdictional problems are presented.

I. *Venue.*

The defendants, Secretary of Health, Education and Welfare and Commissioner of Food and Drugs claim that venue is improper as to twenty-six of the thirty-seven plaintiff corporations. These twenty-six are not incorporated in the State of Delaware.

[fol. 46] The applicable venue statute, 28 U. S. C. 1391(e) reads:

> "A civil action in which each defendant is an officer or employee of the United States or any agency thereof acting in his official capacity or under color of legal authority, or an agency of the United States, may, except as otherwise provided by law, be brought in any judicial district in which: (1) a defendant in the action resides or (2) the cause of action arose, or (3) any real property involved in the action is situated, or (4) the plaintiff resides if no real property is involved in the action."

Defendants admit that the pharmaceutical companies incorporated in Delaware are residents of Delaware within 28 U. S. C. 1391(e)(4). They maintain that the other plaintiffs fall without the bounds of the venue provision because they do not reside in the forum state.

28 U. S. C. 1391(e) does not define residence as applied to corporations. Elsewhere in the venue statute, however, at 28 U. S. C. 1391(c) it is provided:

> "A corporation may be sued in any judicial district in which it is incorporated or licensed to do business or is doing business, and such judicial district shall be regarded as the residence of such corporation for venue purposes."

Plaintiffs argue that this broad definition of residence should be applied to the twenty-six contested parties. Defendant counters that 28 U. S. C. 1391(c) applies only to corporations appearing as defendants and not to plaintiff

corporations because it refers only to corporations which "may be sued."

The interpretation of 28 U. S. C. 1391(c) presents no novel question. There is a classic split of authority among the federal courts as to whether the statute applies to defendant corporations only or to plaintiff and defendant [fol. 47] corporations alike.[2] Nor do the commentators find ground for agreement.[3]

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[2] Defendant corporations only:

Chicago & North Western Ry. Co. v. Davenport, 94 F. Supp. 83 (S. D. Iowa 1950); United Merchants & Manufacturers Inc. v. United States, 123 F. Supp. 435 (M. D. Ga. 1954) [Dicta]; Albright & Friel, Inc. of Delaware v. United States, 142 F. Supp. 607 (E. D. Pa. 1956); Nebraska-Iowa Bridge Corporation v. United States, 158 F. Supp. 796 (D. Neb. 1958); Robert E. Lee & Co. v. Veatch, 301 F. 2d 434 (4 Cir. 1961) cert. den. 371 U. S. 813 (1962).

Plaintiff and defendant corporations:

Freiday v. Cowdin, 83 F. Supp. 516 (S. D. N. Y. 1949); Hadden v. Barrow, Wade, Guthrie & Co., 105 F. Supp. 530 (N. D. Ohio 1952); Southern Paperboard Corporation v. United States, 127 F. Supp. 649 (S. D. N. Y. 1955); Eastern Motor Express, Inc. v. Espenshade, 138 F. Supp. 426 (E. D. Pa. 1956); Standard Insurance Company v. Isbell, 143 F. Supp. 910 (E. D. Tex. 1956); Travelers Insurance Company v. Williams, 164 F. Supp. 566 (W. D. N. C. 1958) aff'd 265 F. 2d 531 (4 Cir. 1959); Wear-Ever Aluminum, Inc. v. Sipos, 184 F. Supp. 364 (S. D. N. Y. 1960); Consolidated Sun Ray, Inc. v. Steel Insurance Company of America, 190 F. Supp. 171 (E. D. Pa. 1961).

[3] Defendant corporations only:

1 Moore, Federal Practice 1503 (2d ed. 1950); Ohlinger's Federal Practice (Rev. ed.), Vol. 1-A, p. 297; Comment, "The Corporate Plaintiff and Venue under Section 1391(c) of the Judicial Code, 28 Univ. Chi. L. Rev. 112 (1960); Case note, 48 Va. L. Rev. 968 (1962).

Plaintiff and defendant corporations:

Wright, Federal Courts, § 42 (1963); Wechsler, Federal Jurisdiction and the Revision of the Judicial Code, 13 Law & Contemporary Problems 216, 240 note 126; Note, The Proposed Revision of the Federal Judicial Code, 60 Harv. L. Rev. 424 (1947); Case note, 76 Harv. L. Rev. 641 (1963); 1 Barron and Holtzoff, Federal Practice and Procedure, 387-88 (Rev. ed. 1960) citing note, Federal Venue and the Corporate Plaintiff: Judicial Code § 1391(c); 28 Ind. L. J. 256 (1953) and note, Federal Venue and the Corporate Plaintiff, 37 Ind. L. J. 363 (1962).

Those courts which conclude that 28 U. S. C. 1391(c) redefined the law of corporate residence for corporations as plaintiffs as well as corporations as defendants rely on interpretation of the last words of the section, "and such judicial district shall be regarded as the residence of such corporation for venue purposes." These words, it is argued, would be superfluous unless applied to corporations as plaintiffs, for the first part of the section grants the right to sue corporations as defendants where they are incorporated, or licensed to do business, or are actually doing business.

[fol. 48] Judge Dimock's statement is representative:

> "I do not feel at liberty to attribute to Congress any * * * tautology. The statute first gives permission to sue a corporation in any district where it is incorporated or licensed or doing business. It then declares that such district shall be regarded as its residence. No one has suggested any reason for that declaration unless it was to give permission to the corporation to sue others in such district in addition to the previously given permission given to others to sue the corporation in any such district." Southern Paperboard Corporation v. United States, 127 F. Supp. 649, 650 (S. D. N. Y. 1955).

Professor Moore has found a meaning for the disputed words which does not comport with the above.

> "The language of the first clause of subsection (c) restricts the subsection to a corporation which 'may be sued.' And this restriction does not make superfluous the second, and concluding clause that 'such judicial district [in which the corporation is incorporated or licensed to do business or is doing business] shall be regarded as the residence of such corporation for venue purposes.' This clause serves a purpose in laying venue, in a transitory action, in a defendant's district where there are multiple defendants residing

in different districts of the same state; and also in the case where defendants reside in different divisions of the same district or different districts in the same state. * * *" 1 Moore, Federal Practice 1503 (2d ed. 1963).

Nonetheless, Moore does not place his chief reliance on this interpretation in deciding that the statute defines residence for corporate defendants only. He emphasizes the fact that the Reviser's Note fails to indicate any intention to effect what would be a far-reaching change as to residence of corporate plaintiffs.

[fol. 49] This position is seconded in the recent opinion, Robert E. Lee & Co., Inc. v. Veatch, 301 F. 2d 434 (4 Cir. 1961), cert. den. 371 U. S. 813 (1962). There the court concluded that Congress would have designed a more sweeping language for Section 1391(c), such as using "all corporations" in the second clause "instead of the restrictive term 'such corporation'", if Congress had intended to do more than codify the rule of Neirbo Co. v. Bethlehem Shipbuilding Corp., Ltd., 308 U. S. 165 (1939), [that a corporation waives its venue privilege not to be sued in a state by obtaining a license to do business there].

Because of the well-balanced forces of reason on either side of this controversy a gentlemanly disagreement will no doubt continue among the courts and commentators until settled by Congress or the Supreme Court. This court is persuaded by those who argue that Congress did not intend the sweeping change which plaintiffs assert and that for purposes of 28 U. S. C. 1391(c) residence is defined only for corporate defendants. The court also holds that the residence of a corporation for purposes of 28 U. S. C. 1391(e) is defined in Section 1391(c). The twenty-six corporations which are not incorporated in Delaware are not properly before the court as plaintiffs in the present action.

II. *The PMA and Standing to Sue.*

The next jurisdictional objection raised by the defendants concerns the standing to sue of the PMA. It is asserted that there is no actual controversy between PMA and the defendants. The regulations promulgated by the Commissioner do not apply to the Association; it neither manufactures nor distributes drugs and it has no occasion, therefore, to either label drug products or advertise them.

The PMA claims to be harmed in a strict dollars and cents fashion by the disputed regulations. The Association points out that under Article III of its by-laws membership dues are based on the annual business of its members. [fol. 50] Rules which affect the income of its members therefore affect PMA.

It is not in its own right, however, but as the representative of some 140 drug companies that this court finds PMA to have standing to sue. In National Motor Freight Traffic Association, Inc. v. United States, certain associations of motor carriers sought to set aside a decision of the Interstate Commerce Commission. The Government argued that the plaintiffs lacked standing to sue because they were associations of carriers rather than the carriers actually affected by the contested order. The lower court agreed with the Government's contention holding that the associations were not qualified to sue because they suffered no legally cognizable injury "except in the remote sense that the problems of their members are their concern." National Motor Freight Traffic Association, Inc. v. United States, 205 F. Supp. 592, 593 (D. C. 1962), aff'd 372 U. S. 246 (1963).

The Supreme Court specifically rejected this ground for decision:

> "The appellants are associations of motor carriers, authorized under 49 USC § 5b, and perform significant functions in the administration of the Interstate Commerce Act, including the representation of member carriers in proceedings before the Commission. Since

individual member carriers of appellants will be aggrieved by the Commission's order, and since appellants are proper representatives of the interests of their members, appellants have standing to challenge the validity of the Commission's order in the District Court." National Motor Freight Traffic Association, Inc. v. United States, 372 U. S. 246, 247 (1963).

The defendants here make much of the Supreme Court's reference to the authorization of motor carrier associations under 49 U. S. C. § 5b. That section, however, does no more than insulate associations approved by the I. C. C. [fol. 51] from violation of the antitrust laws. The crux of the opinion centers on the association as a representative of members who are individually harmed. In that sense, the PMA is similar to the associations in the Motor Freight Traffic case. It represents its members before the Food and Drug administration just as the motor carrier associations appeared in their members' behalf before the I. C. C.

The PMA is a proper representative of the interests of its member drug companies and has standing to challenge the validity of the defendant Commissioner's regulations in this Court.

III. *Propriety of a Judicial Determination at This Time.*

Next the defendants put forward two related arguments which go to the propriety of adjudication at this stage in the proceedings. First, they say that there is no actual controversy between the plaintiffs and defendants as required by the Declaratory Judgment Act, 28 U. S. C. § 2201.[4] Second, they maintain that regulations interpretive in nature, are reviewable only as they may later be

[4] Plaintiffs also claim to be here under § 10 of the Administrative Procedure Act, 5 U. S. C. A. § 1009. Since the court finds that they are properly here for a declaratory judgment it is not necessary to discuss the procedure for review of administrative rule making.

called into question in an enforcement action and not upon their promulgation.

If a regulation is final and a justiciable controversy exists as to its legality, the regulation is ripe for review. A justiciable controversy arises where a plaintiff is confronted with substantial present or imminent harm. The regulations before the court are final and a justiciable controversy exists. The very presence of a threat of harm makes the regulations ready for review. Davis, Administrative Law Treatise, § 21.07.

Defendants say that plaintiffs should not be permitted a declaratory judgment but should have to await an enforcement proceeding before they can call the contested regulations into question. Plaintiffs may have judicial [fol. 52] review of interpretive regulations upon their promulgation without awaiting some ultimate enforcement. Frozen Food Express v. United States, 351 U. S. 40 (1956); Federal Trade Commission v. Nash-Finch Company, 288 F. 2d 407 (D. C. Cir. 1961). They need not await an action which would only make the threat of harm more pressing. The possibility of harm is already apparent to this court. The regulations in issue have placed them in a dilemma. Either they must comply with the every time requirement and incur the costs of changing over their promotional material and labeling or they must follow their present course and risk prosecution. It is of no moment that the Attorney General and not the Food and Drug Administration may enforce these rules. Nor does it matter that the Attorney General has not yet threatened enforcement. Surely, the Commissioner does not announce regulations which he does not intend to enforce by any and every lawful means. From the plaintiffs' point of view danger is imminent. The regulations of which they complain are ripe for review. The declaratory judgment procedure is specifically suited for the determination of controversies where the plaintiffs must either comply with a contested regulation or continue their present course of conduct at their peril. To bar the courts to plaintiffs would be to do an injustice.

IV. *The Attorney General as an Indispensable Party.*

The defendants next argue that the action cannot proceed because an indispensable party, the Attorney General, has not been joined. They point out that proceedings to enforce the Act or to restrain violations of the Act are to be brought in the name of the United States and that it is the Attorney General in his discretion who is granted authority to bring actions enforcing the Act.

Going back to first principles, indispensable parties are persons who have such an interest in a controversy that a final decree cannot be concluded without affecting that interest. 3 Moore, Federal Practice, 2156 (2d ed. 1963). [fol. 53] It would seem unnecessarily cumbersome to hold that the Attorney General is such a party here. The decree sought here does not operate against the Attorney General except in a secondary fashion. He will not be forced to do anything no matter how the court decides. It is the defendants upon whom the benefit or blight of this decision will fall. The decree will expend itself on the defendants and not the Attorney General. The Attorney General is not a party indispensable to the instant litigation. See Federal Trade Commission v. Nash-Finch Company, supra.

V. *The Present Controversy as an Unconsented Suit Against the United States.*

Finally, defendants argue that this litigation is an unconsented suit against the United States.

The point out that the doctrine of sovereign immunity intervenes where the relief sought would interfere with the public administration or restrain the Government from acting or compel it to act. One of the cases cited in accord with this proposition is Larson v. Domestic and Foreign Commerce Corp., 337 U. S. 682 (1949). However, in Larson a significant exception is noted:

> "There may be, of course, suits for specific relief against officers of the sovereign which are not suits

against the sovereign. * * * [W]here the officer's powers are limited by statute, his actions beyond those limitations are considered individual and not sovereign actions. The officer is not doing the business which the sovereign has empowered him to do or he is doing it in a way which the sovereign has forbidden. His actions are 'ultra vires' his authority and therefore may be made the object of specific relief. It is important to note that in such cases the relief can be granted, without impleading the sovereign, only because of the officer's lack of delegated power." Larson v. Domestic and Foreign Commerce Corp., Ibid. at 689-90.

[fol. 54] In their complaint plaintiffs assert:

"20. These regulations are arbitrary and capricious and not in accordance with law, and constitute an unwarranted and unlawful directive to plaintiff companies in excess of the defendants statutory authority and short of statutory right, and contrary to the statutory provisions on which they purport to be based. * * *"

The relief plaintiffs seek is a declaration that the statutory provisions on which the contested regulations are based "do not impose, or authorize the defendants to impose" the requirements which the regulations embody.

This court does not regard plaintiffs' claim that defendants have acted outside the scope of their authority as frivolous. As the Larson case notes, a suit challenging the unauthorized actions of government officials is not a suit against the United States. This action may go forward in the absence of the United States consent to be sued. See, Philadelphia Company v. Stimson, 223 U. S. 605 (1912).

The decision of the merits of this case does not require as lengthy discussion as does negotiation of the procedural maze leading to the merits. The proposition is simple: Congress has enacted legislation setting out rules which

must be complied with if a drug is to be properly branded. The Commissioner of Food and Drugs has issued regulations interpreting the Act of Congress. Plaintiffs attack these regulations.

Regulations of the type with which the court is here concerned are valid unless unreasonable or inconsistent with the statute. Davis, Administrative Law Treatise, § 5.05 (1958). The statute and the disputed regulation are here set out.

"Sec. 502. A drug or device shall be deemed to be misbranded—

* * *

[fol. 55] "(e)(1) If it is a drug, unless (A) its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula), (i) the established name (as defined in subparagraph (2)) of the drug, if such there be, and (ii), in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient . . . and (B) for any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient: *Provided*, That to the extent that compliance with the requirements of clause (A)(ii) or clause (B) of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary."

"Section 1.104(g), 28 Fed. Reg. 6375 (June 20, 1963):

"§ 1.104 Drugs; statement of ingredients.

* * *

"(g)(1) If the label or labeling of a prescription drug bears a proprietary name or designation for the drug or any ingredient thereof, the established name, if such there be, corresponding to such proprietary name or designation, shall accompany each appearance of such proprietary name or designation. The established name shall be placed in direct conjunction with the proprietary name or designation, and the relationship between the proprietary name or designation and the established name shall be made clear by use of a phrase such as 'brand of,' preceding the established name, or by brackets surrounding the established name.

[fol. 56] "(2) The established name shall be printed in letters that are at least half as large as the letters comprising the proprietary name or designation with which it is joined, and the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, layout, contrast, and other printing features."

It is clear from the legislative history that the chief concern of Congress in enacting § 502(e) was the prominent display on labeling of the generic name of a drug. Congress intended to put an end to the previous common practice whereby drug companies would mention the generic name of a drug in an inconspicuous place in microscopic print in order to enhance the value of their own trade name. Congress took pains to assure that the generic name would be printed in type large enough to be seen. This was accomplished by specifying that the generic name be printed in type at least half as large as that used for the trade name.

Not only was Congress concerned with the size of the display of the generic name, it was also concerned with the position of that display. To that end, Congress re-

quired that the generic name be placed "prominently" on labeling. This was the concern of Congress. It is necessarily the concern of the court.

Congress did not specify what it meant by prominent display. Would one mention of the generic name in juxtaposition with the first mention of the trade name suffice? In printed matter comprising several pages should the generic name be mentioned on each page at least once, perhaps at the top of the page? Congress laid down no guide lines.

The defendant Commissioner has interpreted the language of Congress with a broad sweep. He says that the generic name must appear at every mention of the trade [fol. 57] name. His interpretation is inconsistent with the statute. The very word which he has seized on to support the every time requirement belies the argument that Congress intended the generic name be used every time. If Congress had intended that the generic name appear every time the brand name appears there would be no reason to use the word "prominently". The use of the word shows Congress was concerned that the generic name appear in a conspicuous place. If the generic name appeared with every mention of the trade name the requirement of prominence would be unnecessary.

The defendants maintain that the legislative history indicates the adoption by Congress of the every time requirement. They rely heavily upon a statement by Senator Kefauver in which the Senator explained the Conference Committee's rejection of an amendment offered by Congressman O'Brien in the House. The O'Brien amendment would have required that the generic name appear "at the first place, and at the most conspicuous place if other than the first place, at which such proprietary name for such drug . . . is used. . . ." 108 Cong. Rec. 21081 (1962).

Kefauver explained,

"This limitation was not accepted by the conferees. Thus the established name of a prescription drug must

appear in type at least half as large as the trade name wherever the latter is used in drug promotional matter, including package inserts, and so forth." 108 Cong. Rec. 22039 (1962).

First, it is not clear that Kefauver's characterization of the O'Brien amendment as a limitation is accurate. Second, Kefauver's term "wherever" is not free from ambiguity. It could mean that the generic name must appear each time the trade name is mentioned, On the other hand, it could mean that the generic name must appear on a label or brochure or medicine box wherever the trade name is used. Apparently Kefauver favored the every time requirement. [fol. 58] But nowhere in the legislative history is there evidence to show that other members of the Congress favored the every time requirement or that they were aware that "prominently" should have a special meaning.

The views of Senator Kefauver, in this instance, cannot override what the court believes is the general Congressional intent. This is especially true since the expression of those views are circumscribed and open to doubt.

If Congress had meant that the generic name should appear with every mention of the trade name, it could have said so. It has not. It has said only that the generic name must appear prominently. The st ute will not bear the interpretation which the defendants have put upon it.

Submit order in accordance herewith.

Wilmington, Delaware
April 30, 1964

[fol. 59]

IN THE UNITED STATES DISTRICT COURT

UNITED STATES DICTRICT COURT
DISTRICT OF DELAWARE
WILMINGTON 1

Chambers of
CALEB M. WRIGHT
Chief Judge

May 19, 1964

Alexander L. Nichols, Esq.
Morris, Nichols, Arsht & Tunnell
du Pont Building
Wilmington, Delaware 19801

Alexander Greenfeld, Esquire
United States Attorney
Federal Building
Wilmington, Delaware

Re: Abbott Laboratories, et al. v. Celebrezze, C. A. 2737

Gentlemen:

I have read the proposed orders submitted by plaintiffs and defendants. The only difference of substance is that the third paragraph of the proposed order submitted by plaintiffs is not included in the proposed order submitted by the Government.

I see no reason to require counsel to meet with me with respect to the form of order which I propose to sign. I will give parties one week for the plaintiffs to submit their reasons for insisting upon the inclusion of paragraph 3 in said order as submitted by them, and the same period of time for the defendants to make known their insistence that said paragraph be excluded from the proposed order.

Very sincerely yours,

CALEB M. WRIGHT,
Chief Judge.

CMW:pcg
cc—Edward G. Pollard, Clerk

[fol. 60]

IN THE UNITED STATES DISTRICT COURT

Letterhead of

COVINGTON & BURLING
Union Trust Building
Washington 5, D. C.

REpublic 7-5900

May 26, 1964

Hon. Caleb M. Wright
Chief Judge
United States District Court
for the District of Delaware
Federal Building
Wilmington, Delaware

Re: Abbott Laboratories, et al. v.
Celebrezze, et al., C. A. 2737

Dear Judge Wright:

This letter, in response to Your Honor's letter of May 19, 1964, sets forth the plaintiffs' reasons for maintaining that the judgment to be entered should contain an injunction, as provided for in paragraph 3 of their proposed form of order, against the defendants' enforcement of the regulations which have been found to be invalid.

The Complaint in this action requested both a declaratory judgment and injunctive relief. (Complaint, p. 15). In the Court's opinion of April 30, 1964, Your Honor characterized the relief requested by the plaintiffs and the nature of the action as follows (pp. 4-5):

> "[The plaintiffs] . . . claim that the statute does not direct or authorize the defendant Commissioner to impose the [every time] requirement and that the Commissioner's regulations are therefore null and void.

> They seek a declaratory judgment to that effect and an injunction restraining defendants from enforcing the [fol. 61] disputed regulation. The plaintiffs assert that in the absence of such relief they will be forced to choose between flouting the regulation and possibly incurring penalties or reprinting great quantities of advertising material which already complies with the statute as plaintiffs interpret it."

The plaintiffs' Motion for Summary Judgment was not limited to only a part of the relief requested in the Complaint, and we believe that plaintiffs are entitled to a judgment for all of the requested relief, in view of the Court's opinion holding the regulations reviewable and invalid.

It is wholly appropriate for the judgment to contain both a declaration of the regulations' invalidity and an injunction against their enforcement. As Professor Moore points out,

> "The declaratory action offers both an alternative and cumulative remedy, not an exclusive one. . . . Hence a prayer for coercive relief may properly be combined with a prayer for a declaratory judgment; and the judgment on the merits may likewise combine both remedies, and couple, with a declaratory judgment, injunctive relief. . . ." 6 Moore, *Federal Practice* 3047 (2d ed. 1953). (Footnotes omitted.)

In suits to review actions of administrative agencies, the same "ripeness" standard is applicable whether the suit is one for a declaratory judgment or for an injunction. 3 Davis, *Administrative Law* 312 (1938). Thus, the Court having determined that the regulations at issue in this case were ripe for review, the elements necessary for the entry of an injunction have already been found by the Court.

Basically, the injunction is required to afford the successful plaintiffs the protection, to which they believe they

are entitled under the Court's decision, from possible action by FDA personnel inconsistent with the Court's declaration of the regulations invalidity, whether in administrative [fol. 62] proceedings before the agency or in connection with a seizure or other type of enforcement measure.

The plaintiff companies and the other members of the Pharmaceutical Manufacturers Association, as a continuing matter, are constantly required to deal with personnel at all levels of the Food and Drug Administration on such matters as the labeling for drugs and the contents of package inserts and other labeling or advertising materials. The inclusion of the injunction as prayed for in the Complaint is the logical and proper method of insuring that there will be uniform recognition by all of the agency's personnel that no efforts, formal or informal, should be made to enforce these regulations which have been determined by this Court to be invalid and beyond the agency's authority. This is particularly necessary because of the large number of FDA personnel who have responsibilities relating to labeling and advertising, and the various ways in which they deal with these matters.

Including an injunction in the Court's order is the only way to insure that its judgment will be effective. In this connection, we refer to *National Hairdressers' & C. Ass'n* v. *Philad Co.*, 41 F. Supp. 701 (D. Del. 1941), an opinion written by Judge Biggs which was affirmed *per curiam* by the Third Circuit. 129 F. 2d 1020 (3d Cir. 1942). The action there was by an alleged infringer of a patent for a declaration of the patent's invalidity and for an injunction against infringement suits by the patent owner. The Court held the patent invalid, and then determined that an injunction should also issue:

> "The relief granted to [plaintiff] . . . and those on whose behalf his suit was brought should be completely effective and obviate the necessity or possibility of suits by [defendant] . . . against members of the class

represented by [plaintiff] . . . based upon alleged infringement of [the patent held to be invalid] . . . " 41 F. Supp. at 708.

[fol. 63] The reasoning of Judge Biggs was made more explicit in his opinion on a motion for rehearing:

"Assuming that a patent is held to be invalid . . . in a declaratory judgment suit, . . . the owner of the patent can still maintain infringement suits in other jurisdictions. As a defense the plaintiff in the declaratory judgment suit . . . can maintain a plea of res adjudicata in bar of the action. In the light of this fact, in the case at bar, in order to avoid a multiplicity of infringement suits against the members of [plaintiff's] . . . class, in each of which the defendant could maintain a plea of res adjudicata, it is proper to grant injunctive relief." 41 F. Supp. at 709.

The only difference between that case and the present one is that here the defendants are officers of the Federal Government. However, the principles governing the relief to which a successful plaintiff is entitled are the same whether the defendant is a private party or a Federal officer. 6 Moore, *Federal Practice* ¶ 56.26[3] (2d ed. 1953). This is especially true here, where the regulations have been held invalid, since there is no *proper* governmental interest which would be affected by an injunction against the regulations' enforcement.

We respectfully submit that the inclusion of the requested injunction is the desirable way of informing the defendants and all persons under their authority that, under penalty of contempt, they may not attempt to enforce the invalid regulations.

Respectfully yours,

Gerhard A. Gesell.

cc: Alexander Greenfeld, Esq.
William W. Goodrich, Esq.

pc

[fol. 64]

IN THE UNITED STATES DISTRICT COURT

May 28, 1964

Honorable Caleb M. Wright
Judge, United States District Court
District of Delaware
Federal Building
Wilmington, Delaware

Re: Abbott Laboratories, et al. v. Celebrezze, et al.—Civil Action No. 2737.

Dear Judge Wright:

Mr. Goodrich has communicated with our office and has asked us to indicate to you that the Order which the Government has submitted in the above-captioned matter deletes any provision relating to an injunction for the following two reasons:

"(1) The opinion of April 30, 1964 said nothing about an injunction. Instead it indicated to us that the Plaintiffs were entitled to relief in the form of 'a declaration that the statutory provisions on which the contested regulations are based "do not impose, or authorize the defendants to impose" the requirements which the regulations embody.' (p. 19).

(2) The Court has held that this is not a suit to restrain the Government from acting or compel it to act. A sweeping injunction against not only the officers who have acted 'ultra vires' but also against all employees of the Department of Health, Education, and Welfare and the Food and Drug Administration would be inconsistent with the idea that this is not a suit against the United States."

[fol. 65] If we can be of any further assistance to you in this matter, please let us know.

Sincerely,

ALEXANDER GREENFELD,
United States Attorney.

By: WILLIAM J. WIER, JR.,
Assistant United States Attorney.

WJW:mjl

[fol. 66]

IN THE UNITED STATES DISTRICT COURT

JUDGMENT—June 1, 1964

This cause having come on to be heard upon the Complaint and Motions of the respective parties, and the matter having been briefed and argued by counsel for the respective parties and maturely considered by the Court, and the Court having filed herein its Opinion dated April 30, 1964, thereupon, in conformity with said Opinion.

IT IS, this 1 day of June, 1964 HEREBY DECLARED, ADJUDGED AND ORDERED by the Court as follows:

(1) That plaintiffs, American Home Products Corporation, Baxter Laboratories, Inc., Cutter Laboratories, The Dow Chemical Company, Chas. Pfizer & Co., Inc., Philips Roxane, Inc., G. D. Searle & Co., Sterling Drug Inc., The Upjohn Company, Vale Chemical Company, Inc., Warner-Lambert Pharmaceutical Company, and Pharmaceutical Manufacturers Association (as representative of its member companies), have standing to sue in this Court for the relief prayed in this action, and their Motion for Summary Judgment is granted.

(2) That Sections 1.104(g)(1) and 1.105(b)(1) of the General Regulations for the Enforcement of the Federal Food, Drug and Cosmetic Act, 28 Fed. Reg. 6375 (June 20,

1963), issued by the defendant Commissioner of Food and Drugs acting under authority delegated to him by the defendant Secretary of Health, Education and Welfare, insofar as these sections require that the established name of a prescription drug must accompany each appearance of such drug's proprietary name or designation, are null and void and of no effect, and the statutory provisions on which they are based do not impose, or authorize the defendants to impose, the requirements which they embody.

[fol. 67] (3) That the defendants and each of them, and all persons acting under their direction and authority, or in active concert or participation with them, are hereby perpetually enjoined and restrained from enforcing or causing to be enforced, or from attempting to enforce or to cause to be enforced, by any administrative action or civil or criminal proceeding, the requirements of said regulations enumerated in paragraph (2) hereof.

(4) That defendants' Motion to Dismiss and for Summary Judgment is denied as to the plaintiffs named in paragraph (1) hereof.

(5) That the Complaint is dismissed without prejudice as to the remaining plaintiffs for lack of proper venue.

(6) That the respective parties shall bear their own costs of this action.

Caleb M. Wright, *C. J.*

Approved as to Form:

Morris, Nichols, Arsht & Tunnell, Alexander L. Nichols, William S. Megonigal, Jr., *Attorneys for Plaintiffs.*

Attorneys for Defendants.

[fol. 68]

IN THE UNITED STATES COURT OF APPEALS

FOR THE THIRD CIRCUIT

No. 15054

ABBOTT LABORATORIES; ET AL.

v.

ANTHONY J. CELEBREZZE, SECRETARY OF HEALTH, EDUCATION AND WELFARE, and GEORGE P. LARRICK, COMMISSIONER OF FOOD AND DRUGS

ABBOTT LABORATORIES; ALCON LABORATORIES, INC.; ALLERGAN PHARMACEUTICALS; AMERICAN CYANAMID COMPANY; AMES COMPANY, INC.; BARNES-HIND PHARMACEUTICALS, INC.; BREWER & COMPANY, INC.; BURROUGHS WELLCOME & CO. (U.S.A.) INC.; CARTER PRODUCTS, INC.; HOFFMAN-LA ROCHE, INC.; HYNSON, WESTCOTT AND DUNNING INCORPORATED; JOHNSON & JOHNSON; ELI LILLY AND COMPANY; MALLINCKRODT CHEMICAL WORKS; THE S. E. MASSENGILL COMPANY; MEAD JOHNSON & COMPANY; MERCK & CO., INC.; THE NORWICH PHARMACAL COMPANY; OLIN MATHIESON CHEMICAL CORPORATION; ORGANON INC.; PARKE, DAVIS & COMPANY; A. H. ROBINS COMPANY, INCORPORATED; ROWELL LABORATORIES, INC.; SCHERING CORPORATION; SHERMAN LABORATORIES; SMITH KLINE & FRENCH LABORATORIES, Appellants.

Appeal From the United States District Court for the District of Delaware.

Argued April 2, 1965

Before HASTIE and FREEDMAN, *Circuit Judges*, and WEBER, *District Judge*.

[fol. 69]

OPINION OF THE COURT—Filed November 1, 1965

PER CURIAM.

The named appellants in the above entitled case are some, but not all, of the plaintiffs who joined in the complaint for declaratory judgment and injunctive relief.

We find no prejudicial error in the dismissal of the complaint as to these plaintiffs, and that action will be affirmed.

[fol. 70]

IN THE UNITED STATES COURT OF APPEALS

FOR THE THIRD CIRCUIT

No. 15,054

[Title omitted]

On Appeal From the United States District Court for the District of Delaware.

Present: HASTIE and FREEDMAN, *Circuit Judges*, and WEBER, *District Judge*.

JUDGMENT—November 1, 1965

This cause came on to be heard on the record from the United States District Court for the District of Delaware and was argued by counsel.

On consideration whereof, it is now here ordered and adjudged by this Court that paragraph five of the judgment of the District Court, filed June 1, 1964, be and the same is hereby affirmed.

Attest:

Ida O. Creskoff, Clerk.

[File endorsement omitted]

[fol. 71]

IN THE UNITED STATES COURT OF APPEALS

FOR THE THIRD CIRCUIT

No. 15055

ABBOTT LABORATORIES; ET AL.

v.

ANTHONY J. CELEBREZZE, SECRETARY OF HEALTH, EDUCATION AND WELFARE, and GEORGE P. LARRICK, COMMISSIONER OF FOOD AND DRUGS, Appellants.

Appeal From the United States District Court for the District of Delaware.

Argued April 2, 1965

Before: HASTIE and FREEDMAN, *Circuit Judges*, and WEBER, *District Judge*.

OPINION OF THE COURT—Filed November 1, 1965

By WEBER, *District Judge*

This is an appeal from a declaratory judgment and injunction granted to plaintiffs in the District Court which holds that regulations issued and promulgated by defendants, the Secretary of Health, Education and Welfare, and the Commissioner of Food and Drugs are null and void and not authorized by the statute on which they are based. The injunction restrains the defendants and all parties acting under them from enforcing or attempting to enforce the regulations.

[fol. 72] The statute involved is popularly known as the "Drug Amendments of 1962", which added the provisions in question to the Federal Food, Drug and Cosmetic Act, as amended. 21 U.S.C. § 301 et seq. (The Act).

§ 502 (e)(1)(B) of the Act, 21 U.S.C. 352 (e)(1)(B) provided that the labeling of a prescription drug shall be considered "misbranded" unless the established or generic name of the drug is printed prominently on the label in type half as large as any brand or proprietary name. § 502 (n) of the Act contains a similar requirement for advertising matter concerning the drug. Penalties are provided for "misbranding."

The generic name or the established name of a drug is its chemical name, a common name, or an official name used in an official compendium. The proprietary name is the name given by the manufacturer to designate its source of manufacture and to differentiate its product from the same or chemically similar drugs from other manufacturers.

§ 502 (e)(1)(B), 21 U.S.C. 352 (e)(1)(B) contains a provision that to the extent that compliance with the requirements is impracticable, exceptions shall be established by regulations promulgated by the Secretary.

§ 701 (a), 21 U.S.C. 371 (a) grants the authority to the Secretary to promulgate regulations for the efficient enforcement of the Act, except as otherwise provided in that section.

§ 701 (e)(1) of the Act provides the procedure to be employed for the issuance, amendment, or repeal of any regulations under specific sections of the Act, including the filing and disposition of objections thereto by full hearing, the issuance of final orders thereon by the Secretary, and the provision for appeal thereon to the Circuit Court of Appeals. The sections of the Act in question here were not covered by the hearing appeal process recited above.

Pursuant to the authority to promulgate regulations, the Commissioner, as the delegate of the Secretary, issued the [fol. 73] regulations in question here, which provided that under the provisions of § 502 (e)(1)(B), (the labeling requirement), and § 502 (n), (the advertising requirement) of the Act, *each time* the trade name is used on labels or labeling, or in advertisements of prescription drugs, the established name shall also be used prominently and in type half as large. (21 C.F.R. 1.104 (g)(1) and 1.105 (b)(1); 28 Fed. Reg. 6375 and 6376). These regulations were adopted in accordance with the procedure provided by § 4 of the Administrative Procedure Act, 5 U.S.C. 1003, after publication of notice of intent, and the submission of comments and objections by interested parties.

Plaintiffs brought this action in the District Court praying for declaratory judgment and injunctive relief. They rely on the existence of a Federal question, 28 U.S.C. 1331, the Declaratory Judgment Act, 28 U.S.C. 2201, and § 10 of the Administrative Procedure Act, 5 U.S.C. 1009 for jurisdiction. They contend that the *each time* requirements of the regulations are invalid as beyond the requirements of the Act.

The District Court found it unnecessary to rule whether § 10 of the Administrative Procedure Act provided a basis for review of the regulations. It took cognizance of the case under the Declaratory Judgment Act on the grounds that the regulations placed plaintiffs in a position of peril and imminent danger, and that the regulations in question were ripe for review. It not only declared the regulations void because the statute would not bear the interpretation placed upon it, but also issued a sweeping injunction against the enforcement thereof.

Questions of venue of the District Court for all of the many plaintiffs, the standing of a trade association as a party, the inclusion of the Attorney General as a necessary party, and the status of the case as an unconsented suit against the United States were disposed of by the Court, and by reason of the conclusions reached herein, will not be discussed.

[fol. 74] The basic question on appeal here is one of justiciability. May the district court review, under the Declaratory Judgment Act, an interpretive regulation of the Commission issued under authority of the statute, where Congress has not provided for judicial review of the sections in question? Furthermore, was such review within the statutory scheme of regulation imposed by Congress when it specifically provided for judicial review of other regulations authorized under certain specific sections of the Act, as set forth in § 10 (e)(1), 21 U.S.C. 371? We believe that the answer would be the same under the provisions of § 10 of the Administrative Procedure Act, which imposes essentially the same requirements for justiciability as the Declaratory Judgment Act.

A District Court of the United States is limited to those cases over which Congress has granted it jurisdiction. To a large extent the provisions for judicial review of administrative agency action are not applicable to the District Courts, but are placed under the jurisdiction of the Courts of Appeal. Those cases arising from the District Courts which review administrative regulations are largely based on statutory provisions for such review. *Frozen Food Express Co.* v. *United States*, 351 U. S. 40 (1956), was reviewed under the statutory scheme for review of I.C.C. orders by a specially constituted District Court, 28 U.S.C. 1336. *Columbia Broadcasting System, Inc.* v. *United States*, 316 U. S. 407 (1942) arose under § 402 (a) of the Communications Act of 1934, 47 U.S.C. § 402 (a), which provided for judicial review of certain orders of the Federal Communications Commission by a specially constituted District Court, with direct appeal therefrom to the Supreme Court. Under § 402 (b) of that Act review of other types of orders are available only through an appeal to the Court of Appeals of the District of Columbia.

It seems clear to this Court that the intent of Congress was that the administrative regulations for which no review was specifically provided prior to enforcement were those [fol. 75] interpretive regulations which represented the

Commissioner's interpretation of the meaning of the Act. The regulations in question are not those having the force and effect of law by virtue of authority delegated by the Act; they are not an "adjudication" and they are not an "order" and "licensing" under the definitions of § 2 (d) of the Administrative Procedure Act, 5 U.S.C. 1001 (d), as a standard for determination of final agency action as required for judicial review under § 10 of that Act.

The regulations in question were adopted pursuant to § 4 of the Administrative Procedure Act, 5 U.S.C. 1003, which provided for a hearing on the proposed rules before their promulgation. In such a case, the intent of Congress as shown by the specific review provisions of the Act, 21 U.S.C. 371 (e), was to preclude judicial review prior to the enforcement stage. It may be noted that in § 502 (e)(1)(B), Congress has provided for exemption regulations for the labeling requirements where compliance is impracticable. No attempt has been made by plaintiffs to secure relief under that provision.

It has been frequently held that judicial review of such preliminary administrative determination does not fit the statutory scheme of Congress. As was stated in *Ewing* v. *Mytinger & Casselberry*, 339 U. S. 594 (1950), at pp. 600-601:

> "Congress made numerous administrative determinations under the Act[1] reviewable by the Courts.[2] But it did not place the finding of probable cause under § 304 (a) in that category. This highly selective manner in which Congress has provided for judicial review reinforces the inference that the only review of the issue of probable cause which Congress granted was the one provided for in the libel suit. Cf. *Switchmen's Union* v. *Board*, 320 U.S. 297, 305-306."

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[1] The Act in question here.

[2] Footnote omitted.

[fol. 76] As has been recently stated by the Supreme Court in *Whitney National Bank* v. *Bank of New Orleans*, 379 U. S. 411 (1965) at p. 420:

> "Congress has set out in the Bank Holding Company Act of 1956 a carefully planned and comprehensive method for challenging Board determinations. That action by Congress was designed to permit an agency, expert in banking matters, to explore and pass on the ramifications of a proposed bank holding company arrangement. To permit a district court to make the initial determination of a plan's propriety would substantially decrease the effectiveness of the statutory design."

and at page 422:

> "That Congress has not expressly provided that the statutory procedure is to be exclusive does not require a different conclusion."

In addition to the policy of Congress in limiting the administrative matters for which judicial review was provided, which did not include the sections of the Act in question, there are serious obstacles to the use of the Declaratory Judgment Act here as a basis of jurisdiction.

> "A declaratory judgment, like other forms of equitable relief, should be granted only as a matter of judicial discretion, exercised in the public interest. *Brillhart* v. *Excess Insurance Co.*, 316 U. S. 491; *Great Lakes Dredge & Dock Co.* v. *Huffman*, 319 U. S. 293, 297-98; H.R. Rep. No. 1264, 73rd Cong. 2d Sess. p. 2; Borchard, Declaratory Judgments (2d ed. 1941) pp. 312-14. It is always the duty of a court of equity to strike a proper balance between the needs of the plaintiff and the consequences of giving the desired relief. Especially where government action is involved, courts [fol. 77] should not intervene unless the need for

equitable relief is clear, not remote or speculative." *Eccles* v. *Peoples Bank*, 333 U. S. 426, at p. 431 (1948).

The regulations in question are advisory statements as opposed to legislative rules. Cf. *Standard Scale Co.* v. *Farrell*, 249 U. S. 571 (1919). The Act does not give them the force of law, they rise no higher than the terms of the Act itself.

The Declaratory Judgment Act confines the remedy to be limited to an actual "case or controversy". There must be proof of threatened enforcement action that would cause irreparable harm; the judgment sought must conclusively settle a specific controversy between the parties. *Public Service Comm'n* v. *Wycoff*, 344 U. S. 237 (1952).

The case must be appropriate for judicial determination. The relief is available only for a "concrete case admitting of an immediate and definitive determination of the legal rights of the parties in an adversary proceeding upon the facts alleged . . . ." *Aetna Life Insurance Co.* v. *Haworth*, 300 U. S. 227, 241 (1937).

In the case in question the district court was asked for an advisory opinion rather than a concrete decision. It was asked to substitute its discretion for an administrative discretion as to the meaning of the Act. No specific case was presented, no immediate prosecution threatened. The administrative intention was expressed but had not yet come to fruition.

> "The judicial power does not extend to the determination of abstract questions. *Muskrat* v. *United States*, 219 U. S. 346, 361; *Liberty Warehouse Co.* v. *Grannis*, 273 U. S. 70, 74; *Willing* v. *Chicago Auditorium Assn.*, 277 U. S. 274, 289; *Nashville, C. & St. L. Ry Co.* v. *Wallace*, 288 U. S. 249, 262, 264." *Ashwander* v. *Tennessee Valley Authority*, 297 U. S. 288, at p. 324 (1936)

The threat of enforcement must be real, and not merely implied by the existence of the law and regulations. This [fol. 78] would require the exercise of administrative dis-

cretion by the agency and also by the Attorney General. There was no threat of enforcement facing the plaintiffs here sufficient to give an adequate basis for declaratory relief. *United Public Workers* v. *Mitchell*, 330 U.S. 75, (1946).

Perhaps, the closest parallel to the instant case is *Helco Products Co.* v. *McNutt*, 137 F. 2d 681 (D. C. Cir. 1943), which involved an administrative interpretation of a section of the same Act by the Commissioner. The Court details the stages of exercise of discretion between an administrative interpretation and prosecution. The Court concluded at p. 683:

> "We conclude that the present case was not an appropriate one for declaratory judgment . . . The Supreme Court has said the pronouncements, policies and programs of a government administrative agency do not give rise to a justiciable controversy, save as they have fruition in action of a definite and concrete character, constituting an actual or threatened interference with the rights of persons complaining." (citing *Ashwander* v. *T.V.A.*, supra).

The jurisdiction of the District Court in this case is likewise limited by equitable principles that such relief as is demanded here is available only in the absence of an adequate remedy at law. *Beacon Theatres* v. *Westover*, 359 U. S. 500, (1958), *Douglas* v. *Jeannette*, 319 U. S. 157 (1943). Congress has provided a variety of avenues of legal remedy; the exemption provision in the statute where compliance is impracticable, the opportunity to be heard in the rule making proceedings of § 4 of the Administrative Procedure Act; the opportunity to test the interpretation under the enforcement procedures provided for "misbranding", which are (1) seizure proceedings, (2) injunction proceedings, or (3) criminal prosecution. § 301 (a) and (b), 21 U.S.C. 331 (a) and (b). Likewise, if enforcement should be attempted under the new drug clearance pro- [fol. 79] cedures of § 505, 21 U.S.C. 355, or the antibiotic

certification, § 507, 21 U.S.C. 357, there are provisions for administrative hearing and review by the Court of Appeals. Ultimately, final recourse to the District Court for relief under the Declaratory Judgment Act or the Administrative Procedure Act, § 10 in a concrete factual setting involving an actual controversy, is not ruled out at a later stage in the administrative process.

We, therefore, hold that in view of the policy of Congress limiting prior judicial review of administrative actions under this Act to specific sections, not including the ones in question, and in view of the absence of an "actual case or controversy" required for justiciability under the Declaratory Judgment Act, the action of the district court was beyond its permissible area of discretion and the judgment must be vacated, the injunction dissolved, and the action dismissed.

An appropriate order will be entered.

[fol. 80]

IN THE UNITED STATES COURT OF APPEALS

FOR THE THIRD CIRCUIT

No. 15,055

[Title omitted]

On appeal from the United States District Court for the District of Delaware.

Present: HASTIE and FREEDMAN, *Circuit Judges*, and WEBER, *District Judge*.

JUDGMENT—November 1, 1965

This cause came on to be heard on the record from the United States District Court for the District of Delaware and was argued by counsel.

On consideration whereof, it is now here ordered and adjudged by this Court that the judgment of the District

Court, filed June 1, 1964, except as to paragraph five, be, and the same is hereby vacated, the injunction dissolved, and the cause remanded to the District Court with directions to dismiss the complaint in accordance with the opinion of this Court.

Attest:

Ida O. Creskoff, Clerk.

[File endorsement omitted]

[fol. 81] Clerk's Certificate to foregoing transcript (omitted in printing).

[fol. 82]

SUPREME COURT OF THE UNITED STATES

No. 824, October Term, 1965

ABBOTT LABORATORIES, ET AL., Petitioners,

v.

JOHN W. GARDNER, SECRETARY OF HEALTH, EDUCATION AND WELFARE, ET AL.

ORDER ALLOWING CERTIORARI—February 28, 1966

The petition herein for a writ of certiorari to the United States Court of Appeals for the Third Circuit is granted, and the case is placed on the summary calendar.

And it is further ordered that the duly certified copy of the transcript of the proceedings below which accompanied the petition shall be treated as though filed in response to such writ.

Office-Supreme Court, U.S.
FILED
DEC 1 51965
JOHN F. DAVIS, CLERK

No. [redacted] 39

Supreme Court of the United States

OCTOBER TERM, 1965

ABBOTT LABORATORIES; ALCON LABORATORIES, INC.; ALLERGAN PHARMACEUTICALS; AMERICAN CYANAMID COMPANY; AMERICAN HOME PRODUCTS CORPORATION; AMES COMPANY, INC.; BARNES-HIND PHARMACEUTICALS, INC.; BAXTER LABORATORIES, INC.; BREWER & COMPANY, INC.; BURROUGHS WELLCOME & CO. (U.S.A.) INC.; CARTER PRODUCTS, INC.; CUTTER LABORATORIES; THE DOW CHEMICAL COMPANY; HOFFMANN-LA ROCHE INC.; HYNSON, WESTCOTT AND DUNNING INCORPORATED; JOHNSON & JOHNSON; ELI LILLY AND COMPANY; MALLINCKRODT CHEMICAL WORKS; THE S. E. MASSENGILL COMPANY; MEAD JOHNSON & COMPANY; MERCK & CO., INC.; THE NORWICH PHARMACAL COMPANY; OLIN MATHIESON CHEMICAL CORPORATION; ORGANON INC.; PARKE, DAVIS & COMPANY; CHAS. PFIZER & CO., INC.; PHILIPS ROXANE, INC.; A. H. ROBINS COMPANY, INCORPORATED; ROWELL LABORATORIES, INC.; SCHERING CORPORATION; G. D. SEARLE & CO.; SHERMAN LABORATORIES; SMITH KLINE & FRENCH LABORATORIES; STERLING DRUG INC.; THE UPJOHN COMPANY; VALE CHEMICAL COMPANY, INC.; WARNER-LAMBERT PHARMACEUTICAL COMPANY; PHARMACEUTICAL MANUFACTURERS ASSOCIATION, *Petitioners,*

v.

ANTHONY J. CELEBREZZE, Secretary of Health, Education and Welfare, and GEORGE P. LARRICK, Commissioner of Food and Drugs, *Respondents.*

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

(NAMES OF COUNSEL ON INSIDE COVER)

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Supreme Court of the United States

OCTOBER TERM, 1965

No. ____

ABBOTT LABORATORIES; ALCON LABORATORIES, INC.; ALLERGAN PHARMACEUTICALS; AMERICAN CYANAMID COMPANY; AMERICAN HOME PRODUCTS CORPORATION; AMES COMPANY, INC.; BARNES-HIND PHARMACEUTICALS, INC.; BAXTER LABORATORIES, INC.; BREWER & COMPANY, INC.; BURROUGHS WELLCOME & CO. (U.S.A.) INC.; CARTER PRODUCTS, INC.; CUTTER LABORATORIES; THE DOW CHEMICAL COMPANY; HOFFMANN-LA ROCHE INC.; HYNSON, WESTCOTT AND DUNNING INCORPORATED; JOHNSON & JOHNSON; ELI LILLY AND COMPANY; MALLINCKRODT CHEMICAL WORKS; THE S. E. MASSENGILL COMPANY; MEAD JOHNSON & COMPANY; MERCK & CO., INC.; THE NORWICH PHARMACAL COMPANY; OLIN MATHIESON CHEMICAL CORPORATION; ORGANON INC.; PARKE, DAVIS & COMPANY; CHAS. PFIZER & CO., INC.; PHILIPS ROXANE, INC.; A. H. ROBINS COMPANY, INCORPORATED; ROWELL LABORATORIES, INC.; SCHERING CORPORATION; G. D. SEARLE & CO.; SHERMAN LABORATORIES; SMITH KLINE & FRENCH LABORATORIES; STERLING DRUG INC.; THE UPJOHN COMPANY; VALE CHEMICAL COMPANY, INC.; WARNER-LAMBERT PHARMACEUTICAL COMPANY; PHARMACEUTICAL MANUFACTURERS ASSOCIATION, *Petitioners*,

v.

ANTHONY J. CELEBREZZE, Secretary of Health, Education and Welfare, and GEORGE P. LARRICK, Commissioner of Food and Drugs, *Respondents*.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

Petitioners pray that a writ of certiorari issue to review the judgments of the United States Court of Appeals for the Third Circuit in its cases No. 15055 and No. 15054.

OPINIONS BELOW

The opinions of the Court of Appeals, as yet unreported, appear at Appendix A, p. 1a, *infra* (case No. 15055), and Appendix B, p. 10a, *infra* (case No. 15054). The opinion of the United States District Court for the District of Delaware (Chief Judge Caleb M. Wright) is reported at 228 F. Supp. 855 and appears at Appendix C, p. 12a, *infra*.

JURISDICTION

The judgment of the Court of Appeals in its case No. 15055 was entered on November 1, 1965. Appendix D, p. 28a, *infra*. Its judgment in No. 15054, a cross-appeal decided on the same record from the District Court, also was entered on November 1, 1965. Appendix E, p. 29a, *infra*. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

QUESTIONS PRESENTED

I

Federal officials promulgated and published in the Federal Register regulations for the enforcement of a statute. The regulations command all companies in the prescription drug industry to take specified action, and the Federal officials propose to implement the regulations. Compliance by these companies will cause them grave and irreparable injury. Noncompliance, on the other hand, will render the companies subject to civil and criminal prosecutions, seizure proceedings and harmful administrative actions. The question is whether, on the complaint of these companies, the legality of the regulations can be determined under the Declaratory Judgment Act and the Administrative Procedure Act.

II

Whether, under 28 U.S.C. § 1391(e), the statute recently enacted to liberalize venue requirements in actions against Federal officials, a corporation may be a resident of, and thus entitled to sue in a Federal District Court in, a state other than the state of its incorporation?

STATUTES AND REGULATIONS INVOLVED

Statutes:

Declaratory Judgment Act, 28 U.S.C. §§ 2201-02:

"§ 2201. Creation of remedy.

"In a case of actual controversy within its jurisdiction, except with respect to Federal taxes, any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

"§ 2202. Further relief.

"Further necessary or proper relief based on a declaratory judgment or decree may be granted, after reasonable notice and hearing, against any adverse party whose rights have been determined by such judgment."

Administrative Procedure Act, § 10, 60 Stat. 243 (1946), 5 U.S.C. § 1009:

"Sec. 10. Except so far as (1) statutes preclude judicial review or (2) agency action is by law committed to agency discretion—

"(a) Right of review.—Any person suffering legal wrong because of any agency action, or ad-

versely affected or aggrieved by such action within the meaning of any relevant statute, shall be entitled to judicial review thereof.

"(b) Form and venue of action.—The form of proceeding for judicial review shall be any special statutory review proceeding relevant to the subject matter in any court specified by statute or, in the absence or inadequacy thereof, any applicable form of legal action (including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus) in any court of competent jurisdiction. Agency action shall be subject to judicial review in civil or criminal proceedings for judicial enforcement except to the extent that prior, adequate, and exclusive opportunity for such review is provided by law.

"(c) Reviewable acts.—Every agency action made reviewable by statute and every final agency action for which there is no other adequate remedy in any court shall be subject to judicial review. Any preliminary, procedural, or intermediate agency action or ruling not directly reviewable shall be subject to review upon the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final shall be final for the purposes of this subsection whether or not there has been presented or determined any application for a declaratory order, for any form of reconsideration, or (unless the agency otherwise requires by rule and provides that the action meanwhile shall be inoperative) for an appeal to superior agency authority."

Judicial Code, § 1391(e), 28 U.S.C. § 1391(e):

"§ 1391. Venue generally.

* * * * *

"(e) A civil action in which each defendant is an officer or employee of the United States or any agency thereof acting in his official capacity or under color of legal authority, or an agency of the United

States, may, except as otherwise provided by law, be brought in any judicial district in which: (1) a defendant in the action resides, or (2) the cause of action arose, or (3) any real property involved in the action is situated, or (4) the plaintiff resides if no real property is involved in the action."

The foregoing statutory provisions govern the jurisdictional and procedural questions presented. The issue on the merits involves Section 502(e)(1) of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1050 (1938), as amended by § 112(a) of the Drug Amendments of 1962, 76 Stat. 790, 21 U.S. C. § 352(e)(1), and Section 502(n) of that Act, added by § 131(a) of the Drug Amendments of 1962, 76 Stat. 791, 21 U.S.C. § 352(n), which appear at Appendix F, p. 31a, *infra*.

Regulations:

Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act, §§ 1.104(g), 1.105(b), 28 Fed. Reg. 6375, 6376 (1963), 21 C. F. R. §§ 1.104(g), 1.105(b) (1965):

"§ 1.104 Drugs; statement of ingredients.

* * *

"(g) (1) If the label or labeling of a prescription drug bears a proprietary name or designation for the drug or any ingredient thereof, the established name, if such there be, corresponding to such proprietary name or designation, shall accompany each appearance of such proprietary name or designation. The established name shall be placed in direct conjunction with the proprietary name or designation, and the relationship between the proprietary name or designation and the established name shall be made clear by use of a phrase such as 'brand of,' preceding the established name, or by brackets surrounding the established name.

"(2) The established name shall be printed in letters that are at least half as large as the letters comprising the proprietary name or designation with which it is joined, and the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, layout, contrast, and other printing features.

"§ 1.105 Prescription-drug advertisements.

* * *

"(b) (1) If an advertisement for a prescription drug bears a proprietary name or designation for the drug or any ingredient thereof, the established name, if such there be, corresponding to such proprietary name or designation, shall accompany each appearance of such proprietary name or designation. The established name shall be placed in direct conjunction with the proprietary name or designation, and the relationship between the proprietary name or designation and the established name shall be made clear by use of a phrase such as 'brand of,' preceding the established name, or by brackets surrounding the established name.

"(2) The established name shall be printed in letters that are at least half as large as the letters comprising the proprietary name or designation with which it is joined, and the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, layout, contrast, and other printing features."

STATEMENT

Petitioners are thirty-seven companies that manufacture and distribute prescription drugs and the Pharmaceutical Manufacturers Association ("PMA"), an association of which these companies and other prescription

drug companies are members. (R. 5a).[1] Each prescription drug company is directly affected by the challenged regulations. In the regular course of business it affixes labels to its prescription drugs and distributes labeling and advertising material in connection with such drugs. (R. 6a). Each company generally assigns a proprietary (brand) name to each prescription drug which it distributes, and these brand names appear on printed matter (including labels, labeling and advertising) relating to the particular prescription drug. (R. 8a).

Proceedings below

On June 20, 1963, after a formal rule making proceeding in accordance with Section 4 of the Administrative Procedure Act, 60 Stat. 238 (1946), 5 U. S. C. § 1003, regulations issued by the respondent Larrick, Commissioner of Food and Drugs, were published in the Federal Register. 28 Fed. Reg. 6375.[2] These regulations, as will be developed in more detail below, require that on all printed matter the established (generic) name of a prescription drug must be repeated each time the drug's proprietary name is used, no matter how many times the proprietary name is mentioned in a particular label, labeling piece or advertisement. Petitioners objected to this "every time" requirement when it was proposed in the rule making proceeding, but respondent Larrick refused to alter his proposal.[3]

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[1] "R." references are to the pages of the Joint Appendix printed for use in the Court of Appeals. Nine copies of the Joint Appendix have been filed with the Clerk of this Court pursuant to Rule 21(4).

[2] The regulations were stated to be issued under the authority delegated to Commissioner Larrick by the Secretary of Health, Education and Welfare. See 28 Fed. Reg. 6375.

[3] Proposed regulations were published on February 14, 1963, 28 Fed. Reg. 1448. In response, the petitioning companies, either individually or through PMA, submitted comments contending, *inter alia*, that respondents could not lawfully impose the "every time" requirement. (R. 10a-11a). Petitioners' contention was rejected by the respondents when the final regulations were issued.

Shortly after the regulations issued, petitioners filed a complaint in the United States District Court for the District of Delaware, asserting that the respondents were not authorized to impose the "every time" requirement and requesting a declaratory judgment to that effect and an injunction against enforcement of the regulations. (R. 3a-16a). The District Court's jurisdiction was invoked under Sections 1331 and 1337 of the Judicial Code, 28 U. S. C. §§ 1331, 1337, the Declaratory Judgment Act and Section 10 of the Administrative Procedure Act. (R. 3a).

Respondents moved to dismiss on jurisdictional and procedural grounds and for summary judgment if the merits should be reached. (R. 17a-20a). Petitioners filed a cross-motion for summary judgment. (R. 21a-22a). The case was heard on these motions. No answer was filed. No affidavits were filed by the respondents disputing any of the factual allegations in the complaint.

Of the thirty-eight petitioners, there were twelve—the PMA and eleven individual companies incorporated in Delaware (see R. 3a-5a)—as to which venue was clearly proper. The District Court held that a justiciable controversy was presented and rejected other jurisdictional arguments which respondents interposed as obstacles to an adjudication on the merits. The District Court reached the merits, held the regulations invalid, and enjoined enforcement of the regulations. (R. 66a-67a). The Court dismissed from the action those petitioners not incorporated in Delaware.

Cross-appeals were taken by the respondents and by those petitioners not incorporated in Delaware to the United States Court of Appeals for the Third Circuit. On respondents' appeal (case No. 15055), the Court of Appeals, in an opinion by District Judge Weber, held that no justiciable

controversy was presented because the regulations were "interpretive" and there had been no threat of prosecution. Accordingly, as to petitioners incorporated in Delaware, the Court did not reach the other jurisdictional issues decided by the District Court nor did it reach the merits. The District Court's venue ruling—dismissing from the action those petitioners not incorporated in Delaware—was affirmed by the Court of Appeals in its case No. 15054. The Court of Appeals has stayed the issuance of its mandate in both cases.

Nature of the regulations

As has been noted, the regulations at issue here were adopted after a formal rule making proceeding and were published in the Federal Register. 28 Fed. Reg. 6375. They were entitled "Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act." *Ibid.* They were made effective upon their publication. *Id.* at 6377.

Section 1.104(g) of the regulations ordered that the established (generic) name of a prescription drug "shall accompany each appearance" of that drug's brand name on labels and labeling for the drug.[4] The same requirement was imposed for advertisements of prescription drugs by Section 1.105(b) of the regulations. These regulations are applicable to advertisements and to "brochures, mailing pieces, detailing pieces, file cards, bulletins, price lists, catalogs, house organs, literature reprints, and similar pieces of printed matter." § 1.105 (*l*), 28 Fed. Reg. 6377, 21 C. F. R.

[4]The established or generic name of a drug is defined in Section 502(e)(2) of the Act, added by § 112(a) of the Drug Amendments of 1962, 76 Stat. 790, 21 U. S. C. § 352(e)(2). Under that section, the established name of a drug may be a "common or usual name," an "official title" used in an "official compendium," or an "official name" designated by the Secretary under Section 508 of the Act, added by § 111(a) of the Drug Amendments of 1962, 76 Stat. 789, 21 U. S. C. § 358.

§ 1.105(*l*). Each time the brand name of a drug appears on any of these items (which include every piece of printed matter relating to the drug), the regulations require that its established name also be printed.

Compliance with these mandatory regulations would require each company to cease the distribution of printed matter which did not contain an "every time" mention of the established name, to destroy such material and to prepare new material in its place that would be more difficult to read and comprehend and would injure that company's business. (R. 13a-14a). Under Sections 302-04 of the Act, 52 Stat. 1043 (1938), as amended, 21 U. S. C. §§ 332-34, noncompliance with the regulations subjects each company to seizure proceedings, under which valuable drugs can be forfeited, and to criminal prosecutions and injunction proceedings. (R. 9a-10a).[5] Respondents can also attempt to enforce the regulations by refusing to approve the marketing of "new drugs" under Section 505 of the Act, 52 Stat. 1052 (1938), as amended, 21 U. S. C. § 355, and by refusing to certify each batch of antibiotics under Section 507 of the Act, 59 Stat. 463 (1945), as amended, 21 U. S. C. § 357, unless related printed matter complies with the "every time" requirement. See pp. 8a-9a, *infra*.

These drastic remedies can be invoked—even though the drugs are perfectly safe and effective, and even though

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[5]Indeed, Section 1.105 (k) of the regulations, 28 Fed. Reg. 6377, 21 C. F. R. § 1.105(k), provides that any advertisement not in compliance with the "every time" requirement "shall cause stocks of such drug in possession of the person responsible for issuing or causing the issuance of the advertisement . . . to be misbranded under section 502(a) of the act." Sections 301(a) and (b) of the Act, 52 Stat. 1042 (1938), as amended, 21 U. S. C. §§ 331(a), (b), prohibit the "misbranding" of any drug and the introduction into commerce of any "misbranded" drug, and Sections 302-04 of the Act specify the sanctions for violating Section 301.

the established name appears "prominently" on every page in the required type size and no doctor or patient is misled—solely on the ground that the established name does not appear every single time the proprietary name is used.

During the course of argument in the District Court, the mandatory nature of the regulations was emphasized, as the following colloquy reveals:

> "The Court: Mr. Goodrich [counsel for respondents], when your department makes a regulation, I certainly hope that you intend for the drug industry to obey those regulations.
>
> "Mr. Goodrich: We do indeed, sir.
>
> "The Court: If not, you take whatever steps are necessary to enforce them.
>
> "Mr. Goodrich: But the enforcement in the setting of a real case, where we have a piece of promotional material before us, is entirely different from an abstract question which is presented here." (R. 24a).

Respondents' counsel left no doubt that respondents intended petitioners to comply with the regulations and that noncompliance would call into play the drastic enforcement provisions of the Act.

REASONS FOR GRANTING THE WRIT

I

An industry is here confronted with regulations promulgated by Federal officials to enforce a statute carrying severe civil and criminal sanctions. In the opinion of petitioners, with which the District Court agreed, these regulations are contrary to the statute and not authorized by it. Unless there is a means of presenting to a court at once the question whether these regulations are lawful, each member of the industry has two choices: it can comply with the regulations, incurring substantial expense and changing its way of doing business, despite its belief that

the regulations are invalid; or it can defy the regulations, suffer months of delay in clearing applications to market "new drugs" and in obtaining certificates for batches of antibiotics, and await the unilateral decision of enforcement officials as to when, how, and against whom an attempt will be made to impose severe criminal or civil sanctions. Under these circumstances, as stated by the District Court, "to bar the courts to plaintiffs [petitioners] would be to do an injustice." P. 21a, *infra*.

If the Government succeeds in barring the courts to petitioners, thus preventing a straight-forward immediate test of the regulations, an industry confronted with illegal regulations will be obliged as a practical matter to engage in a type of guerrilla warfare with the Government. The Government, having promulgated the regulations, will wait a period of time in the hope that some companies, concerned with the possibility of administrative retaliation in the event of noncompliance, will comply with the regulations even though they believe in good faith that the regulations are illegal. After the illegal regulations have been in effect for some time and there have been some instances of compliance, the Government then at its own time and at its own convenience will select an individual member of the industry for a test case based on an egregious and nontypical example for the purpose of demonstrating the "validity" of the regulations. The Government will cite the facts that the regulations have long been in effect without challenge and that members of the industry have complied with the regulations. By this process of delay and attrition, the Government can create a situation where the regulations have acquired apparent validity although their inherent illegality remains the same. This is no way for Government in a democratic society to deal with those subject to its power.

The basic issue in this case is whether an industry confronted with illegal action by Federal officials should not

have its day in court in order that it can proceed in accordance with an established rule of law equally applicable to all members of the industry.

The Court of Appeals determined that the members of regulated industries are not entitled to their day in court—that in spite of a clear declaration that the regulations would be enforced, the Federal courts have no jurisdiction under either the Declaratory Judgment Act or the Administrative Procedure Act even to consider whether the regulations are within the statutory authority of the officials who promulgated them. This determination conflicts with decisions of this Court. Furthermore, this case is an ideal vehicle for considering the scope and nature of Federal jurisdiction to deal with this pervasive problem of testing, at the time they are officially proclaimed, regulatory requirements affecting every business enterprise within an entire industry. No facts are in dispute. No fact needed to decide the central legal issue will be any different in a future individual enforcement proceeding from the facts as they exist today. The challenged regulations were held invalid by the District Court before the Court of Appeals improperly declined on jurisdictional grounds to consider the matter.

1. On the basic question of justiciability, the issue as seen by both the District Court and the Court of Appeals was one of ripeness—may parties adversely affected by a regulation challenge its legality when it is promulgated or must they act at their peril and await the institution of penal or enforcement proceedings before the legality of the regulation can be judicially determined? In holding that the regulations at issue here were not ripe for review, the Court of Appeals has decided an important question of Federal law in a way that conflicts with decisions of this Court dealing with the review of administrative regulations,

Columbia Broadcasting System, Inc. v. *United States*, 316 U. S. 407 (1942); *Frozen Food Express* v. *United States*, 351 U. S. 40 (1956); and *United States* v. *Storer Broadcasting Co.*, 351 U. S. 192 (1956).

Columbia Broadcasting involved regulations of the FCC which provided that licenses would not thereafter be issued to stations having certain contractual relationships with networks. Even though, as the Court noted, the regulations were not self-executing—they "did not operate of their own force to deny or cancel a license," 316 U. S. at 417—the regulations were held to be ripe for review because of their adverse impact on CBS. The Court, moreover, specifically rejected two contentions accepted here by the Court of Appeals. First, this Court held that the regulations were reviewable even though it was not "certain" that enforcement proceedings would be instituted. 316 U. S. at 417-18. Compare pp. 7a-8a, *infra*.[6] Second, this Court rejected the

[6] The Court of Appeals' insistence that there be a specific threat of enforcement not only conflicts with *Columbia Broadcasting* and the other administrative law decisions of this Court—in none of which was there any such threat—it is also in conflict with this Court's decisions in cases in which the constitutionality of statutes is challenged in actions to enjoin their enforcement. In neither Truax v. Raich, 239 U. S. 33 (1915), nor Pierce v. Society of Sisters, 268 U. S. 510 (1925), for example, had there been an official threat or other governmental enforcement action of any kind when suit was instituted; in each case the threat existed by the nature of the statutory command or prohibition and its obvious viability, and in each case the impact of the challenged statutes upon the plaintiffs sufficed to present a justiciable controversy.

In this case, moreover, that petitioners had a "realistic fear of prosecution," see Poe v. Ullman, 367 U. S. 497, 508 (1961), and that the regulations themselves constituted a threat are confirmed by the position taken by respondents in the District Court when their counsel stated that enforcement proceedings would be instituted if the regulations were not complied with. (R. 24a, 36a). As the District Court observed, "Surely, the Commissioner does not announce regulations which he does not intend to enforce by any and every lawful means." P. 21a, *infra*.

contention that the regulations were reviewable only in an enforcement proceeding:

> "Having adopted this order under its rule-making power, the Commission cannot insist that [plaintiff] . . . be relegated to that judicial review which would be exclusive if the rule-making power had never been exercised and consequently never subjected [plaintiff] . . . to the threatened irreparable injury." 316 U. S. at 421. Compare p. 8a, *infra*.

Storer also involved a licensing regulation of the FCC. The regulation was held reviewable because "the Commission exercised a power of rule-making which controls broadcasters" and the regulations "now operate to control the business affairs of Storer," 351 U. S. at 199—conclusions directly applicable to the regulations at issue here.

This pragmatic approach to the question of ripeness was carried forward in *Frozen Food Express*, a case involving an interpretive report of the ICC in which it rendered its opinion as to the status of certain commodities under an exemption provided by the Interstate Commerce Act for the carriage of agricultural products by motor carriers. Over the contention that the report was not reviewable because it "has no operative effect," 351 U. S. at 46, a position adopted by the Court of Appeals here, pp. 5a, 7a, *infra*, this Court held that the report was reviewable because of its practical impact on carriers:

> "The determination by the Commission that a commodity is not an exempt agricultural product has an immediate and practical impact on carriers who are transporting the commodities . . . . The 'order' of the Commission warns every carrier, who does not have authority from the Commission to transport those commodities, that it does so at the risk of incurring criminal penalties. . . . Where unauthorized operations occur, the Commission may proceed adminis-

> tratively and issue a cease and desist order. . . . The determination made by the Commission is not therefore abstract, theoretical, or academic. . . . The 'order' of the Commission . . . is, indeed, the basis for carriers in ordering and arranging their affairs. . . . The 'order' of the Commission is in substance a 'declaratory' one . . . which touches vital interests of carriers . . . and sets the standard for shaping the manner in which an important segment of the trucking business will be done." 351 U. S. at 43-44.

Frozen Food Express thus plainly establishes, contrary to the Court of Appeals' determination here, that "interpretive" regulations are not *ipso facto* unreviewable.[7] Further, *Frozen Food Express* sets forth the standard for determining the ripeness of regulations for review, a standard that was met in this case, and demonstrates that no "abstract, theoretical, or academic" controversy was presented by these regulations. As in *Frozen Food Express*, the very existence of the regulations "has an immediate and practical impact on" petitioners. Compliance with the regulations requires petitioners to change their method of doing business. On the other hand, noncompliance with the "every time" requirement imposed by the regulations subjects petitioners to the risk of criminal penalties and seizure actions as well as adverse administrative actions. In sum, the petitioners here are in precisely the same situation as that which confronted the carriers in *Frozen Food Express*, and the holding there that a justiciable controversy was presented governs this case.

The Court of Appeals, however, refused to follow *Frozen Food Express* and the other controlling decisions of

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[7] In Lester C. Newton Trucking Co. v. United States, 209 F. Supp. 600, 602 (D. Del. 1962), *aff'd per curiam*, 372 U. S. 702 (1963), the three-judge court followed *Frozen Food Express* and held that an "interpretive opinion" of the ICC was reviewable.

this Court. The Court of Appeals sought to distinguish *Columbia Broadcasting* and *Frozen Food Express*—the Court did not mention the *Storer* case—on the ground that those cases arose under specific statutory review provisions and were not declaratory judgment actions. P. 4a, *infra*.[8] This purported distinction does not bear on the question of ripeness.

This Court has demonstrated that the rules governing justiciability are the same whether suit is brought under specific review provisions or the Declaratory Judgment Act. *Nukk* v. *Shaughnessy*, 350 U. S. 869 (1955), *reversing per curiam* 125 F. Supp. 498 (S. D. N. Y. 1954), was a declaratory judgment action brought to challenge the validity of administrative regulations, the same type of action as that involved here. The District Court held, as did the Court of Appeals here, that the regulations were not ripe for review because there had been no specific threat to enforce the regulations. This Court reversed *per curiam*, saying only:

> "The Court is of opinion that the complaints do present a case and controversy. *Rochester Telephone Corp.* v. *United States*, 307 U. S. 125. The judgment is reversed and the case is remanded for consideration on the merits." 350 U. S. at 869.

The *Rochester* case, although an action brought under a specific statutory review provision, was thus held dispositive in a declaratory judgment action.

The *Nukk* case, in which the Court thought the appropriate decision so clear that it need not even write a full opinion, is of course in accord with decisions of the Court

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[8] In fact, however, both *Frozen Food Express* and *Storer* were actions brought under the Administrative Procedure Act, as well as under the specific statutory provisions applicable to the ICC and FCC, respectively. See 351 U. S. at 42; 351 U. S. at 195.

in which it has spelled out its reasoning. The results reached in the *Columbia Broadcasting, Storer,* and *Frozen Food Express* cases mean that a challenge to a regulation that has an adverse effect on private parties produces a "case or controversy" in the constitutional sense; otherwise, despite the statutory review provisions, each of those cases should have been dismissed for lack of jurisdiction. As the Court has held, the requirement under the Declaratory Judgment Act that there be an "actual controversy" has the same meaning as the constitutional "case or controversy" requirement. *E.g., Public Serv. Comm'n* v. *Wycoff Co.,* 344 U. S. 237, 242 (1952); *United Pub. Workers* v. *Mitchell,* 330 U. S. 75, 89, 93 (1947). The decisions of this Court thus preclude the Court of Appeals' determination that no "actual controversy" existed under the Declaratory Judgment Act.

Furthermore, this case was brought under the Administrative Procedure Act as well as the Declaratory Judgment Act. Whatever may have been the situation prior to the enactment of the APA in 1946, it is now clear that under Section 10 of the APA "final agency action" is reviewable through declaratory judgment and injunction proceedings. See *Rusk* v. *Cort,* 369 U. S. 367, 375 (1962). It is also clear under the *Storer* case that the regulations at issue here constitute "final agency action" within the meaning of the APA. As has already been discussed, *Storer* was a case in which regulations were challenged upon their promulgation and, although a specific statutory review provision was involved in that case, the action was also brought under the APA. The Court held that the regulations were reviewable under the APA:

> "We think respondent had standing to sue at the time it exercised its privilege. The process of rule making was complete. It was final agency action, 5 U.S.C. § 1001(c) and (g) . . ." 351 U. S. at 198.

Here, too, "the process of rulemaking was complete" when the complaint was filed in the District Court. Here, too, the issuance of the regulations by the respondents constituted "final agency action" within the meaning of Section 10 of the APA.[9] It is thus untenable to suggest, as the Court of Appeals held, that the leading administrative law decisions of this Court have no bearing on actions brought under the APA and the Declaratory Judgment Act to challenge administrative regulations.[10]

At the risk of belaboring the obvious, it should be pointed out that Professors Jaffe and Davis, two renowned

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[9]The implication in the Court of Appeals' opinion, p. 5a, *infra*, that the regulations at issue here are not within § 10 of the APA is inexplicable in light of the definition of "agency action" in § 2(g) of the APA, 60 Stat. 238 (1946), 5 U.S.C. § 1001(g), as including "every agency rule . . . ." "Rule" is defined in § 2(c) of the APA, 60 Stat. 237 (1946), 5 U.S.C. § 1001(c), as "any agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy," a definition which clearly encompasses the regulations at issue in this proceeding.

[10]This Court's decisions in Ewing v. Mytinger & Casselberry, Inc., 339 U. S. 594 (1950), and Whitney Nat'l Bank v. Bank of New Orleans, 379 U. S. 411 (1965), relied on by the Court of Appeals, do not affect the *Columbia Broadcasting* line of cases which govern this action. *Ewing* involved an attempt to review a finding of probable cause, not a final regulation. *Whitney Nat'l Bank* rested on the fact that the appropriate agency had never passed upon the contentions urged in the courts; here, petitioners' position as to the illegality of the "every time" requirement had been presented to and rejected by the respondents before this action was filed in the District Court. See n.3, *supra*.

Similarly, although the Court of Appeals stated that Helco Prods. Co. v. McNutt, 137 F. 2d 681 (D. C. Cir. 1943), was perhaps "the closest parallel" to this case, p. 8a, *infra*, *Helco* involved an informal, unpublished letter of the Food and Drug Administration, not formal and purportedly final and effective regulations.

The Court of Appeals' reliance on the provision in § 502(e)(1)(B) for exemptions from the requirements of that section where compliance would be "impracticable" was also misplaced, for in *Storer* this

students of administrative law, have independently recognized the applicability to declaratory judgment actions of the principles announced in cases brought under specific review provisions. Jaffe, *Ripeness and Reviewable Orders in Administrative Law*, 61 Mich. L. Rev. 1273, 1286-87 (1963); 3 Davis, *Administrative Law* § 21.06, at 150-51 (1958). In the words of Professor Davis:

> "In many cases, regulations of the ICC and of the FCC have been challenged by suits for injunctions under the Urgent Deficiencies Act; if a suit under that Act is not premature, no reason is apparent for holding premature an ordinary bill in equity or a declaratory action." *Ibid.* (Footnotes omitted.)[11]

The Court of Appeals' decision can be read as resting in considerable part on the fact that Congress provided for review in the Courts of Appeals of Food and Drug Administration regulations issued under certain provisions of the Act, not including those pursuant to which the regu-

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Court held a regulation reviewable even though the FCC could waive its requirements. See 351 U. S. at 205. Furthermore, the exemption provision applies only to the section of the regulations dealing with labels and labeling and not to the section dealing with advertising, and, finally, petitioners' contention is that the regulations, whether or not compliance would be "practicable," are invalid.

[11]Professor Davis, moreover, specifically mentions the "sound holding" in Toilet Goods Ass'n v. Celebrezze, 235 F. Supp. 648 (S. D. N. Y. 1964), that other regulations issued by these respondents may be challenged in a declaratory judgment action in a District Court. 3 Davis, *Administrative Law* § 21.08, at 45 (Supp. 1965). District Judge Tyler in the *Toilet Goods* case relied heavily on the opinion of the District Court in this case.

After the Court of Appeals' decision in this proceeding, these respondents renewed their motion to dismiss in the *Toilet Goods* case. On December 6, 1965, Judge Tyler reaffirmed his prior ruling that a justiciable controversy was presented and again denied the motion; he has authorized an interlocutory appeal from his action to the Court of Appeals for the Second Circuit under 28 U. S. C. § 1292(b).

lations here were issued, and that therefore Congress meant to preclude review of other FDA regulations.

It should be emphasized, however, that there is no question of reviewability *vel non* presented in this case. As the Court of Appeals itself recognized, p. 8a, *infra*, the validity of the regulations can be determined by a District Court in an enforcement action. Thus, the question is one of ripeness —when, and not whether, the regulations are reviewable— a question which is controlled by the *Columbia Broadcasting* line of cases.

Moreover, to the extent that the decision below is based on an assumed congressional intent to preclude review, it conflicts with this Court's decisions in *Leedom* v. *Kyne*, 358 U. S. 184 (1958), and *Rusk* v. *Cort*, 369 U. S. 367 (1962).

In *Leedom* v. *Kyne* this Court affirmed a judgment of a District Court granting an injunction setting aside an order of the National Labor Relations Board that was not among the kinds of NLRB orders made reviewable by statute in the Courts of Appeals. The members of the Board, named individually as defendants in the District Court suit, conceded in this Court that the District Court had jurisdiction "unless the review provisions of the National Labor Relations Act destroyed it." 358 U. S. at 187. Contrary to the holding of the Court below with respect to the review provisions of the Food, Drug, and Cosmetic Act, this Court held that the specification by Congress of certain NLRB orders as being reviewable in the Courts of Appeals did not by negative implication destroy equitable district-court jurisdiction of suits challenging other kinds of orders.

Decisions of other Courts of Appeals sanctioning district-court suits challenging agency actions not among those made reviewable by the Courts of Appeals are in accord

with *Leedom* v. *Kyne* and equally in conflict with the decision below. *Elmo Division of Drive-X Co.* v. *Dixon*, 348 F.2d 342, 343 (D. C. Cir. 1965) ("Statutory provisions concerning review of agency action by the Courts of Appeals do not in and of themselves . . . preclude District Court jurisdiction"); *Deering Milliken, Inc.* v. *Johnston*, 295 F. 2d 856 (4th Cir. 1961).

In *Leedom* v. *Kyne* the District Court's jurisdiction was founded on 28 U. S. C. § 1337, the statute giving the District Courts jurisdiction of cases arising under acts regulating commerce. In *Rusk* v. *Cort*, an action was brought under Section 10 of the Administrative Procedure Act and the Declaratory Judgment Act by a person located outside the United States who claimed that he had been illegally denied a passport. The Immigration Act specifically authorized declaratory actions by persons located within the United States to challenge the withholding of passports, and it set forth a procedure whereby persons outside the United States could challenge such denials in habeas corpus proceedings. This Court nevertheless held that the APA permitted the institution of declaratory judgment actions by persons not located within the United States. The Court noted the "broad provisions" of the APA and the Declaratory Judgment Act, 369 U. S. at 372, stated that "the Administrative Procedure Act confers the right to judicial review of 'any agency action'," 369 U. S. at 375, and, referring to *Shaughnessy* v. *Pedreiro*, 349 U. S. 48 (1955), and *Brownell* v. *Tom We Shung*, 352 U. S. 180 (1956),[12] concluded:

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[12] The Court in *Shaughnessy* v. *Pedreiro* referred to "the generous review provisions" of the APA and said that they granted "an expanded right of review" and that the APA "is to be given a 'hospitable' interpretation." 349 U. S. at 51. *Brownell* v. *Tom We Shung* also mentions the "expanded mode of review" granted by the APA. 352 U. S. at 185.

> "[T]he Court will not hold that the broadly remedial provisions of the Administrative Procedure Act are unavailable to review administrative decisions under the 1952 [Immigration] Act in the absence of clear and convincing evidence that Congress so intended." 369 U. S. at 379-80.[13]

In short, the Court held in *Leedom* v. *Kyne* and *Rusk* v. *Cort* that statutory provisions authorizing review of certain orders, in the first case, or review by a certain class of persons, in the latter, were not "clear and convincing evidence" that Congress intended to preclude review of other orders or by other persons. The Court of Appeals here, however, reached precisely the opposite conclusion, holding that because certain types of regulations were made specifically reviewable, Congress did not intend judicial review of the regulations at issue in this case.[14]

2. Even if it should be thought that the Court of Appeals' decision does not conflict with decisions of this Court,

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[13]That a strong showing must be made in order to preclude review under the APA is also demonstrated by Schilling v. Rogers, 363 U. S. 666 (1960). Four members of the Court there would have held that the APA was available to review an administrative determination under the Trading with the Enemy Act even though the Act specifically stated that the remedies provided in the Act, which did not include any provision for judicial review so far as the plaintiff there was concerned, shall be "the sole relief and remedy" of claimants of vested property. §7(c), 40 Stat. 1021 (1918), 50 U.S.C. App. §7(c). There is, of course, no such provision in the Food, Drug, and Cosmetic Act.

[14]Indeed, this case is a stronger one for reviewability than *Rusk* v. *Cort*, where there was some legislative history which the dissenting opinion read as reflecting a congressional intent to preclude review. Here, on the other hand, the Court of Appeals did not cite any legislative history material at all to show that Congress even considered precluding review of regulations of the type involved in this proceeding.

it clearly cannot be contended that that decision was compelled by any decision of this Court. Review by this Court is warranted so that the important questions presented can be definitively settled.

This case was brought by the prescription drug industry in order to obtain a prompt judicial determination as to whether there must be compliance with regulations that the industry believed were without statutory basis. The decision of the District Court holding the regulations invalid demonstrates that, at the very least, the industry's belief was and is based on substantial grounds. The alternative to this action—and the result of the Court of Appeals' decision if not reversed—would be a multitude of enforcement proceedings against individual companies which do not comply with the regulations, an alternative which not only leads to unnecessary litigation but which resolves only in piecemeal fashion the question whether the regulations are lawful.

The issue is tendered on cross-motions for summary judgment. It should be resolved. There is no justification for allowing the respondents to hold an industry at hazard under illegal regulations while they sit back, attack particular companies for noncompliance when the occasion seems right, letting others who do not comply go unchallenged, and use all the pressures at their command to force compliance with illegal regulations as the price of administrative authorizations needed to do business.

The public interest would certainly not be served by further delay and uncertainty. As Professor Jaffe has said:

> "The public has an interest in early implementation of policy; the regulated person has a legitimate interest whether to plan, or not to plan, his operation on the basis of a regulation." Jaffe, *supra*, 61 Mich. L. Rev. at 1283.

Or, in the words of a perceptive District Judge who held other regulations issued by these respondents to be reviewable in a declaratory judgment action:

> "[T]o resort to later piecemeal resolution of the controversy in the context of individual enforcement proceedings would be costly and inefficient, not only for the plaintiffs but as well for the public as represented by the defendants." *Toilet Goods Ass'n* v. *Celebrezze*, 235 F. Supp. 648, 651 (S. D. N. Y. 1964). See also *National Van Lines, Inc.* v. *United States*, 326 F. 2d 362, 373 (7th Cir. 1964); *ICC* v. *Atlantic Coast Line R. R.*, 334 F. 2d 46, 51 (5th Cir. 1964), *cert. granted*, 379 U. S. 957 (1965).

Indeed, as stated by one of the respondents in this proceeding:

> "When any interested party feels that one of our regulations is wrong and should be challenged in the courts, we welcome such an action. Court decisions interpreting sections of the law or regulations that have given rise to honest differences of opinion are most helpful to us as guidelines to fair administration." Address of Commissioner George P. Larrick before the Pharmaceutical Manufacturers Association, April 14, 1964, p. 4.

II

The second question presented relates to where actions against Federal officials may be brought. Section 1391(e)(4) of Title 28, enacted in 1962 to liberalize venue requirements for actions against Federal officials,[15] provides that such actions may be brought in any district in

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[15]See S. Rep. No. 1992, 87th Cong., 2d Sess. 2 (1962); H.R. Rep. No. 536, 87th Cong., 1st Sess. 1-2 (1961). The previous venue provisions had resulted in actions against Federal officials being concentrated in the District Court for the District of Columbia, and Section 1391(e) was designed to lessen the burden on that Court by permitting such actions to be brought in courts throughout the country. See S. Rep. No. 1992, *supra*, at 3; H.R. Rep. No. 536, *supra*, at 3.

which "the plaintiff resides . . . ." Petitioners contended that the definition of corporate residence in 28 U.S.C. § 1391(c)—where a corporation is incorporated, licensed to do business or doing business—should be incorporated into the word "resides" in Section 1391(e)(4).[16] The District Court rejected this contention and held that venue was improper as to those petitioners not incorporated in Delaware, and the Court of Appeals affirmed the dismissal of the complaint as to such petitioners. The District Court relied on cases dealing with an analogous question—whether the definition of corporate residence in Section 1391(c) applies to corporate plaintiffs in cases where venue is governed by 28 U. S. C. § 1391(a) —, a question on which, as the District Court noted, p. 15a, *infra*, there is "a classic split of authority" among the lower Federal courts[17] and the commentators.[18] Judge Wright observed:

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[16]The Court so held in Toilet Goods Ass'n v. Celebrezze, 235 F. Supp. 648 (S. D. N. Y. 1964), the only other case arising under Section 1391(e) in which this question has been presented.

[17]*Compare* Freiday v. Cowdin, 83 F. Supp. 516, 517-18 (S. D. N. Y. 1949), *appeal dismissed by consent*, 177 F. 2d 1020 (2d Cir. 1949); Hadden v. Barrow, Wade, Guthrie & Co., 105 F. Supp. 530 (N. D. Ohio 1952); Southern Paperboard Corp. v. United States, 127 F. Supp. 649 (S. D. N. Y. 1955); Eastern Motor Express, Inc. v. Espenshade, 138 F. Supp. 426, 431 (E. D. Pa. 1956); Standard Ins. Co. v. Isbell, 143 F. Supp. 910 (E. D. Tex. 1956); Travelers Ins. Co. v. Williams, 164 F. Supp. 566 (W. D. N. C. 1958); Wear-Ever Aluminum, Inc. v. Sipos, 184 F. Supp. 364 (S. D. N. Y. 1960); and Consolidated Sun Ray, Inc. v. Steel Ins. Co. of America, 190 F. Supp. 171 (E. D. Pa. 1961), *with* Robert E. Lee & Co. v. Veatch, 301 F. 2d 434 (4th Cir. 1961), *cert. denied*, 371 U. S. 813 (1962); Carter-Beveridge Drilling Co. v. Hughes, 323 F. 2d 417 (5th Cir. 1963); Chicago & North Western Ry. v. Davenport, 94 F. Supp. 83 (S. D. Iowa 1950); United Merchants & Mfrs., Inc. v. United States, 123 F. Supp. 435 (M. D. Ga. 1954) (dictum); Albright & Friel, Inc. v. United States, 142 F. Supp. 607 (E. D. Pa. 1956); Nebraska-Iowa Bridge Corp. v. United States, 158 F. Supp. 796 (D. Neb. 1958); and North River Ins. Co. v. Davis, 237 F. Supp. 187 (W. D. Va. 1965).

[18]*Compare* Wright, *Federal Courts* § 42, at 132-33 (1963); 76 Harv. L. Rev. 641 (1963); 1 Barron & Holtzoff, *Federal Practice & Procedure* § 80, at 387-88 (rev. ed. 1960), § 80, at 180 (Supp.

> "Because of the well-balanced forces of reason on either side of this controversy a gentlemanly disagreement will no doubt continue among the courts and commentators until settled by Congress or the Supreme Court." P. 18a, *infra*.

The venue question presented in this case, an issue of statutory construction unaffected by differing circumstances of different cases, is a question of basic importance involving the situs of cases dealing with the legality of actions of Federal officials. It is a question on which the guidance of this Court is needed.

1965), citing Note, 28 Ind. L. J. 256 (1953), and Note, 37 Ind. L. J. 363 (1962); Wechsler, *Federal Jurisdiction and the Revision of the Judicial Code*, 13 Law & Contemp. Prob. 216, 240 n.126 (1948); and Note, 60 Harv. L. Rev. 424, 434-35 (1947), *with* 48 Va. L. Rev. 968 (1962); Comment, 28 U. Chi. L. Rev. 112 (1960); 1 Moore, *Federal Practice* ¶ 0.142 [5.-3], at 1503 (2d ed. 1950); 1-A Ohlinger, *Federal Practice* ¶ 2.3.4, at 297 (1950).

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX A

UNITED STATES COURT OF APPEALS

FOR THE THIRD CIRCUIT

No. 15055

ABBOTT LABORATORIES; ET AL.

v.

ANTHONY J. CELEBREZZE, SECRETARY OF HEALTH, EDUCATION AND WELFARE, AND GEORGE P. LARRICK, COMMISSIONER OF FOOD AND DRUGS,

Appellants

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

Argued April 2, 1965

Before: HASTIE and FREEDMAN, *Circuit Judges*, and WEBER, *District Judge*.

OPINION OF THE COURT

(Filed November 1, 1965)

By WEBER, *District Judge*

This is an appeal from a declaratory judgment and injunction granted to plaintiffs in the District Court which holds that regulations issued and promulgated by defendants, the Secretary of Health, Education and Welfare, and the Commissioner of Food and Drugs are null and void and not authorized by the statute on which they are based. The injunction restrains the defendants and all parties acting under them from enforcing or attempting to enforce the regulations.

The statute involved is popularly known as the "Drug Amendments of 1962", which added the provisions in question to the Federal Food, Drug and Cosmetic Act, as amended. 21 U.S.C. § 301 et seq. (The Act).

§ 502 (e) (1) (B) of the Act, 21 U.S.C. 352 (e) (1) (B) provided that the labeling of a prescription drug shall be considered "misbranded" unless the established or generic name of the drug is printed prominently on the label in type half as large as any brand or proprietary name. § 502 (n) of the Act contains a similar requirement for advertising matter concerning the drug. Penalties are provided for "misbranding."

The generic name or the established name of a drug is its chemical name, a common name, or an official name used in an official compendium. The proprietary name is the name given by the manufacturer to designate its source of manufacture and to differentiate its product from the same or chemically similar drugs from other manufacturers.

§ 502 (e) (1) (B), 21 U.S.C. 352 (e) (1) (B) contains a provision that to the extent that compliance with the requirements is impracticable, exceptions shall be established by regulations promulgated by the Secretary.

§ 701 (a), 21 U.S.C. 371 (a) grants the authority to the Secretary to promulgate regulations for the efficient enforcement of the Act, except as otherwise provided in that section.

§ 701 (e) (1) of the Act provides the procedure to be employed for the issuance, amendment, or repeal of any regulations under specific sections of the Act, including the filing and disposition of objections thereto by full hearing, the issuance of final orders thereon by the Secretary, and the provision for appeal thereon to the Circuit Court of Appeals. The sections of the Act in question here were not covered by the hearing appeal process recited above.

Pursuant to the authority to promulgate regulations, the Commissioner, as the delegate of the Secretary, issued the regulations in question here, which provided that under the provisions of § 502 (e)(1)(B), (the labeling requirement), and § 502 (n), (the advertising requirement) of the Act, *each time* the trade name is used on labels or labeling, or in advertisements of prescription drugs, the established name shall also be used prominently and in type half as large. (21 C.F.R. 1.104 (g)(1) and 1.105 (b)(1); 28 Fed. Reg. 6375 and 6376). These regulations were adopted in accordance with the procedure provided by § 4 of the Administrative Procedure Act, 5 U.S.C. 1003, after publication of notice of intent, and the submission of comments and objections by interested parties.

Plaintiffs brought this action in the District Court praying for declaratory judgment and injunctive relief. They rely on the existence of a Federal question, 28 U.S.C. 1331, the Declaratory Judgment Act, 28 U.S.C. 2201, and § 10 of the Administrative Procedure Act, 5 U.S.C. 1009 for jurisdiction. They contend that the *each time* requirements of the regulations are invalid as beyond the requirements of the Act.

The District Court found it unnecessary to rule whether § 10 of the Administrative Procedure Act provided a basis for review of the regulations. It took cognizance of the case under the Declaratory Judgment Act on the grounds that the regulations placed plaintiffs in a position of peril and imminent danger, and that the regulations in question were ripe for review. It not only declared the regulations void because the statute would not bear the interpretation placed upon it, but also issued a sweeping injunction against the enforcement thereof.

Questions of venue of the District Court for all of the many plaintiffs, the standing of a trade association as a party, the inclusion of the Attorney General as a necessary party, and the status of the case as an unconsented suit against the United States were disposed of by the Court,

and by reason of the conclusions reached herein, will not be discussed.

The basic question on appeal here is one of justiciability. May the district court review, under the Declaratory Judgment Act, an interpretive regulation of the Commission issued under authority of the statute, where Congress has not provided for judicial review of the sections in question? Furthermore, was such review within the statutory scheme of regulation imposed by Congress when it specifically provided for judicial review of other regulations authorized under certain specific sections of the Act, as set forth in §10 (e)(1), 21 U. S. C. 371? We believe that the answer would be the same under the provisions of § 10 of the Administrative Procedure Act, which imposes essentially the same requirements for justiciability as the Declaratory Judgment Act.

A District Court of the United States is limited to those cases over which Congress has granted it jurisdiction. To a large extent the provisions for judicial review of administrative agency action are not applicable to the District Courts, but are placed under the jurisdiction of the Courts of Appeal. Those cases arising from the District Courts which review administrative regulations are largely based on statutory provisions for such review. *Frozen Food Express Co. v. United States*, 351 U. S. 40 (1956), was reviewed under the statutory scheme for review of I.C.C. orders by a specially constituted District Court, 28 U.S.C. 1336. *Columbia Broadcasting System, Inc. v. United States*, 316 U. S. 407 (1942) arose under § 402 (a) of the Communications Act of 1934, 47 U.S.C. § 402 (a), which provided for judicial review of certain orders of the Federal Communications Commission by a specially constituted District Court, with direct appeal therefrom to the Supreme Court. Under § 402 (b) of that Act review of other types of orders are available only through an appeal to the Court of Appeals of the District of Columbia.

It seems clear to this Court that the intent of Congress was that the administrative regulations for which no review was specifically provided prior to enforcement were those interpretive regulations which represented the Commissioner's interpretation of the meaning of the Act. The regulations in question are not those having the force and effect of law by virtue of authority delegated by the Act; they are not an "adjudication" and they are not an "order" and "licensing" under the definitions of § 2 (d) of the Administrative Procedure Act, 5 U.S.C. 1001 (d), as a standard for determination of final agency action as required for judicial review under § 10 of that Act.

The regulations in question were adopted pursuant to § 4 of the Administrative Procedure Act, 5 U.S.C. 1003, which provided for a hearing on the proposed rules before their promulgation. In such a case, the intent of Congress as shown by the specific review provisions of the Act, 21 U.S.C. 371 (e), was to preclude judicial review prior to the enforcement stage. It may be noted that in § 502 (e) (1) (B), Congress has provided for exemption regulations for the labeling requirements where compliance is impracticable. No attempt has been made by plaintiffs to secure relief under that provision.

It has been frequently held that judicial review of such preliminary administrative determination does not fit the statutory scheme of Congress. As was stated in *Ewing v. Mytinger & Casselberry*, 339 U. S. 594 (1950), at p. 600-601:

> "Congress made numerous administrative determinations under the Act[1] reviewable by the Courts[2]. But it did not place the finding of probable cause under § 304 (a) in that category. This highly selective manner in which Congress has provided for judicial review reinforces the inference that the only review of the issue of probable cause which Congress granted was

[1]The Act in question here.
[2]Foot-note omitted.

the one provided for in the libel suit. Cf. *Switchmen's Union v. Board*, 320 U. S. 297, 305-306.".

As has been recently stated by the Supreme Court in *Whitney National Bank v. Bank of New Orleans*, 379 U. S. 411 (1965) at p. 420:

> "Congress has set out in the Bank Holding Company Act of 1956 a carefully planned and comprehensive method for challenging Board determinations. That action by Congress was designed to permit an agency, expert in banking matters, to explore and pass on the ramifications of a proposed bank holding company arrangement. To permit a district court to make the initial determination of a plan's propriety would substantially decrease the effectiveness of the statutory design."

and at page 422:

> "That Congress has not expressly provided that the statutory procedure is to be exclusive does not require a different conclusion."

In addition to the policy of Congress in limiting the administrative matters for which judicial review was provided, which did not include the sections of the Act in question, there are serious obstacles to the use of the Declaratory Judgment Act here as a basis of jurisdiction.

> "A declaratory judgment, like other forms of equitable relief, should be granted only as a matter of judicial discretion, exercised in the public interest. *Brillhart v. Excess Insurance Co.*, 316 U. S. 491; *Great Lakes Dredge & Dock Co. v. Huffman*, 319 U. S. 293, 297-98; H. R. Rep. No. 1264, 73rd Cong. 2d Sess. p. 2; Borchard, Declaratory Judgments (2d ed. 1941) pp. 312-14. It is always the duty of a court of equity to strike a proper balance between the needs of the plaintiff and the consequences of giving the desired relief. Especially where government action is involved, courts

should not intervene unless the need for equitable relief is clear, not remote or speculative." *Eccles v. Peoples Bank*, 333 U. S. 426, at p. 431 (1948).

The regulations in question are advisory statements as opposed to legislative rules. Cf. *Standard Scale Co. v. Farrell*, 249 U. S. 571 (1919). The Act does not give them the force of law, they rise no higher than the terms of the Act itself.

The Declaratory Judgment Act confines the remedy to be limited to an actual "case or controversy". There must be proof of threatened enforcement action that would cause irreparable harm; the judgment sought must conclusively settle a specific controversy between the parties. *Public Service Comm'n v. Wycoff*, 344 U. S. 237 (1952).

The case must be appropriate for judicial determination. The relief is available only for a "concrete case admitting of an immediate and definitive determination of the legal rights of the parties in an adversary proceeding upon the facts alleged . . . ." *Aetna Life Insurance Co. v. Haworth*, 300 U. S. 227, 241 (1937).

In the case in question the district court was asked for an advisory opinion rather than a concrete decision. It was asked to substitute its discretion for an administrative discretion as to the meaning of the Act. No specific case was presented, no immediate prosecution threatened. The administrative intention was expressed but had not yet come to fruition.

"The judicial power does not extend to the determination of abstract questions. *Muskrat v. United States*, 219 U. S. 346, 361; *Liberty Warehouse Co. v. Grannis*, 273 U. S. 70, 74; *Willing v. Chicago Auditorium Assn.*, 277 U. S. 274, 289; *Nashville, C. & St. L. Ry. Co. v. Wallace*, 288 U. S. 249, 262, 264." *Ashwander v. Tennessee Valley Authority*, 297 U. S. 288, at p. 324 (1936)

The threat of enforcement must be real, and not merely implied by the existence of the law and regulations. This would require the exercise of administrative discretion by the agency and also by the Attorney General. There was no threat of enforcement facing the plaintiffs here sufficient to give an adequate basis for declaratory relief. *United Public Workers v. Mitchell*, 330 U.S. 75, (1946).

Perhaps, the closest parallel to the instant case is *Helco Products Co. v. McNutt*, 137 F.2d 681 (D. C. Cir. 1943), which involved an administrative interpretation of a section of the same Act by the Commissioner. The Court details the stages of exercise of discretion between an administrative interpretation and prosecution. The Court concluded at p. 683:

> "We conclude that the present case was not an appropriate one for declaratory judgment . . . The Supreme Court has said the pronouncements, policies and programs of a government administrative agency do not give rise to a justiciable controversy, save as they have fruition in action of a definite and concrete character, constituting an actual or threatened interference with the rights of persons complaining." (citing *Ashwander v. T.V.A.*, supra).

The jurisdiction of the District Court in this case is likewise limited by equitable principles that such relief as is demanded here is available only in the absence of an adequate remedy at law. *Beacon Theatres v. Westover*, 359 U.S. 500, (1958), *Douglas v. Jeannette*, 319 U.S. 157 (1943). Congress has provided a variety of avenues of legal remedy; the exemption provision in the statute where compliance is impracticable, the opportunity to be heard in the rule making proceedings of § 4 of the Administrative Procedure Act; the opportunity to test the interpretation under the enforcement procedures provided for "misbranding", which are (1) seizure proceedings, (2) injunction proceedings, or (3) criminal prosecution. § 301 (a) and (b), 21 U.S.C. 331 (a) and (b). Likewise, if enforcement should be attempted under the new drug clearance procedures of § 505, 21 U.S.C. 355, or the antibiotic certification, § 507, 21 U.S.C. 357, there are

provisions for administrative hearing and review by the Court of Appeals. Ultimately, final recourse to the District Court for relief under the Declaratory Judgment Act or the Administrative Procedure Act, § 10 in a concrete factual setting involving an actual controversy, is not ruled out at a later stage in the administrative process.

We, therefore, hold that in view of the policy of Congress limiting prior judicial review of administrative actions under this Act to specific sections, not including the ones in question, and in view of the absence of an "actual case or controversy" required for justiciability under the Declaratory Judgment Act, the action of the district court was beyond its permissible area of discretion and the judgment must be vacated, the injunction dissolved, and the action dismissed.

An appropriate order will be entered.

APPENDIX B

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 15054

ABBOTT LABORATORIES; ET AL.

v.

ANTHONY J. CELEBREZZE, SECRETARY OF HEALTH, EDUCATION AND WELFARE, AND GEORGE P. LARRICK, COMMISSIONER OF FOOD AND DRUGS

ABBOTT LABORATORIES; ALCON LABORATORIES, INC.; ALLERGAN PHARMACEUTICALS; AMERICAN CYANAMID COMPANY; AMES COMPANY, INC.; BARNES-HIND PHARMACEUTICALS, INC.; BREWER & COMPANY, INC.; BURROUGHS WELLCOME & CO. (U. S. A.) INC.; CARTER PRODUCTS, INC.; HOFFMAN-LA ROCHE, INC.; HYNSON, WESTCOTT AND DUNNING INCORPORATED; JOHNSON & JOHNSON; ELI LILLY AND COMPANY; MALLINCKRODT CHEMICAL WORKS; THE S. E. MASSENGILL COMPANY; MEAD JOHNSON & COMPANY; MERCK & CO., INC.; THE NORWICH PHARMACAL COMPANY; OLIN MATHIESON CHEMICAL CORPORATION; ORGANON INC.; PARKE, DAVIS & COMPANY; [redacted]. H. ROBINS COMPANY, INCORPORATED; [redacted]OWELL LABORATORIES, INC.; SCHERING CORPORATION; SHERMAN LABORATORIES; SMITH KLINE & FRENCH LABORATORIES,

Appellants

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

Argued April 2, 1965

Before HASTIE and FREEDMAN, *Circuit Judges*, and WEBER, *District Judge*.

OPINION OF THE COURT

(Filed November 1, 1965)

PER CURIAM.

The named appellants in the above entitled case are some, but not all, of the plaintiffs who joined in the complaint for declaratory judgment and injunctive relief.

We find no prejudicial error in the dismissal of the complaint as to these plaintiffs, and that action will be affirmed.

APPENDIX C

IN THE

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

Civil Action No. 2737

ABBOTT LABORATORIES; ALCON LABORATORIES, INC.; ALLERGAN PHARMACEUTICALS; AMERICAN CYANAMID COMPANY; AMERICAN HOME PRODUCTS CORPORATION; AMES COMPANY, INC.; BARNES-HIND PHARMACEUTICALS, INC.; BAXTER LABORATORIES, INC.; BREWER & COMPANY, INC.; BURROUGHS WELLCOME & CO. (U.S.A.) INC.; CARTER PRODUCTS, INC.; CUTTER LABORATORIES; THE DOW CHEMICAL COMPANY; HOFFMAN-LAROCHE INC.; HYNSON, WESTCOTT AND DUNNING INCORPORATED; JOHNSON & JOHNSON; ELI LILLY AND COMPANY; MALLINCKRODT CHEMICAL WORKS; THE S. E. MASSENGILL COMPANY; MEAD JOHNSON & COMPANY; MERCK & CO., INC.; THE NORWICH PHARMACAL COMPANY; OLIN MATHIESON CHEMICAL CORPORATION; ORGANON INC.; PARKE, DAVIS & COMPANY; CHAS. PFIZER & CO., INC.; PHILIPS ROXANE, INC.; A. H. ROBINS COMPANY, INCORPORATED; ROWELL LABORATORIES, INC.; SCHERING CORPORATION; G. D. SEARLE & CO.; SHERMAN LABORATORIES; SMITH KLINE & FRENCH LABORATORIES; STERLING DRUG, INC.; THE UPJOHN COMPANY; VALE CHEMICAL COMPANY, INC.; WARNER-LAMBERT PHARMACEUTICAL COMPANY; PHARMACEUTICAL MANUFACTURERS ASSOCIATION,

Plaintiffs,

v.

ANTHONY J. CELEBREZZE, SECRETARY OF HEALTH, EDUCATION AND WELFARE, and

GEORGE P. LARRICK, COMMISSIONER OF FOOD AND DRUGS,

Defendants.

OPINION

WRIGHT, *Chief Judge.*

This action arises under the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, as amended 21 U.S.C. § 301, et seq. ("the Act").

According to § 502(e)(1)(B) of the Act, 21 U.S.C. § 352(e)(1)(B), the labeling of a prescription drug shall cause that drug to be "misbranded" unless the established or generic name of the drug is printed prominently on any label or labeling material, as defined in the Act, in type half as large as any brand or proprietary name.[1]

The proprietary, or brand name, of a prescription drug is used by the manufacturer to identify the source of the drug. The proprietary name distinguishes the drug manufactured by one company from the drug with active ingredients of the same or similar chemical constitution produced by another company. Thus a physician can, if he desires, exercise a choice among sources in prescribing drugs for his patient.

Most prescription drugs also have a non-proprietary or generic name. Such a name may be a systematic chemical name, a common name, or an official name used in some official compendium or designated by the Secretary of Health, Education and Welfare. This is the "established name" which § 502(e)(1)(B) requires to be prominently displayed on drug labeling. If this requirement is not met and a misbranded drug is introduced into interstate commerce (a) the drugs may be seized and forfeited, (b) the introduction of such drugs into interstate commerce may be enjoined, (c) the persons who cause introduction of the misbranded

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[1]The language of § 502(n) of the Act, 21 U.S.C. § 352(n) which applies to advertising is similar. This opinion covers both sections although only § 502(e) is specifically discussed.

drugs into interstate commerce may be subject to criminal prosecution.

In February, 1963, the defendant, Commissioner of Food and Drugs proposed the adoption of certain new regulations under the Act. The final regulations, 28 Fed. Reg. 6375, were promulgated in June, 1963 and were effective on publication. It is these regulations which are under attack in the present proceeding. Under the new regulations the Act is interpreted to require that the established or generic name be placed in conjunction with every appearance of the proprietary name of the drug on labels and advertising.

Thirty-seven drug companies and the Pharmaceutical Manufacturers Association (PMA) have joined as plaintiffs to challenge the every time requirement. They claim that the statute does not direct or authorize the defendant Commissioner to impose the requirement and that the Commissioner's regulations are therefore null and void. They seek a declaratory judgment to that effect and an injunction restraining defendants from enforcing the disputed regulation. The plaintiffs assert that in the absence of such relief they will be forced to choose between flouting the regulation and possibly incurring penalties or reprinting great quantities of advertising material which already complies with the statute as plaintiffs interpret it. This material, including brochures, price lists, catalogues, and labels prominently sets forth the generic name of the prescription drug involved but it does not meet the every time requirement.

At the outset, a host of jurisdictional problems are presented.

I. Venue

The defendants, Secretary of Health, Education and Welfare and Commissioner of Food and Drugs claim that venue is improper as to twenty-six of the thirty-seven plaintiff corporations. These twenty-six are not incorporated in the State of Delaware.

The applicable venue statute, 28 U.S.C. 1391(e) reads:

> "A civil action in which each defendant is an officer or employee of the United States or any agency thereof acting in his official capacity or under color of legal authority, or an agency of the United States, may, except as otherwise provided by law, be brought in any judicial district in which: (1) a defendant in the action resides or (2) the cause of action arose, or (3) any real property involved in the action is situated, or (4) the plaintiff resides if no real property is involved in the action."

Defendants admit that the pharmaceutical companies incorporated in Delaware are residents of Delaware within 28 U.S.C. 1391(e)(4). They maintain that the other plaintiffs fall without the bounds of the venue provision because they do not reside in the forum state.

28 U.S.C. 1391(e) does not define residence as applied to corporations. Elsewhere in the venue statute, however, at 28 U.S.C. 1391(c) it is provided:

> "A corporation may be sued in any judicial district in which it is incorporated or licensed to do business or is doing business, and such judicial district shall be regarded as the residence of such corporation for venue purposes."

Plaintiffs argue that this broad definition of residence should be applied to the twenty-six contested parties. Defendant counters that 28 U.S.C. 1391(c) applies only to corporations appearing as defendants and not to plaintiff corporations because it refers only to corporations which "may be sued."

The interpretation of 28 U.S.C. 1391(c) presents no novel question. There is a classic split of authority among the federal courts as to whether the statute applies to defendant corporations only or to plaintiff and defendant

corporations alike.[5] Nor do the commentators find ground for agreement.[6]

Those courts which conclude that 28 U.S.C. 1391(c) redefined the law of corporate residence for corporations as plaintiffs as well as corporations as defendants rely on

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[5]Defendant corporations only:

Chicago & North Western Ry. Co. v. Davenport, 94 F. Supp. 83 (S.D. Iowa 1950); United Merchants & Manufacturers Inc. v. United States, 123 F. Supp. 435 (M.D. Ga. 1954) [Dicta]; Albright & Friel, Inc. of Delaware v. United States, 142 F. Supp. 607 (E.D. Pa. 1956); Nebraska-Iowa Bridge Corporation v. United States, 158 F. Supp. 796 (D. Neb. 1958); Robert E. Lee & Co. v. Veatch, 301 F.2d 434 (4 Cir. 1961) cert. den. 371 U.S. 813 (1962).

Plaintiff and defendant corporations:

Freiday v. Cowdin, 83 F. Supp. 516 (S.D.N.Y. 1949); Hadden v. Barrow, Wade, Guthrie & Co., 105 F. Supp. 530 (N.D. Ohio 1952); Southern Paperboard Corporation v. United States, 127 F. Supp. 649 (S.D.N.Y. 1955); Eastern Motor Express, Inc. v. Espenshade, 138 F. Supp. 426 (E.D. Pa. 1956); Standard Insurance Company v. Isbell, 143 F. Supp. 910 (E.D. Tex. 1956); Travelers Insurance Company v. Williams, 164 F. Supp. 566 (W.D.N.C. 1958) aff'd. 265 F.2d 531 (4 Cir. 1959); Wear-Ever Aluminum, Inc. v. Sipos, 184 F. Supp. 364 (S. D. N. Y. 1960); Consolidated Sun Ray, Inc. v. Steel Insurance Company of America, 190 F. Supp. 171 (E.D. Pa. 1961).

[6]Defendant corporations only:

1 Moore, Federal Practice 1503 (2d ed. 1950); Ohlinger's Federal Practice (Rev. ed.) Vol. 1-A, p. 297; Comment, "The Corporate Plaintiff and Venue under Section 1391(c) of the Judicial Code, 28 Univ. Chi. L. Rev. 112 (1960); Case note, 48 Va. L. Rev. 968 (1962).

Plaintiff and defendant corporations:

Wright, Federal Courts, § 42 (1963); Wechsler, Federal Jurisdiction and the Revision of the Judicial Code, 13 Law & Contemporary Problems 216, 240 note 126; Note, The Proposed Revision of the Federal Judicial Code, 60 Harv. L. Rev. 424 (1947); Case note, 76 Harv. L. Rev. 641 (1963); 1 Barron and Holtzoff, Federal Practice and Procedure, 387-88 (Rev. ed. 1960) citing note, Federal Venue and the Corporate Plaintiff: Judicial Code § 1391(c); 28 Ind. L. J. 256 (1953) and note, Federal Venue and the Corporate Plaintiff, 37 Ind. L. J. 363 (1962).

interpretation of the last words of the section, "and such judicial district shall be regarded as the residence of such corporation for venue purposes." These words, it is argued, would be superfluous unless applied to corporations as plaintiffs, for the first part of the section grants the right to sue corporations as defendants where they are incorporated, or licensed to do business, or are actually doing business.

Judge Dimock's statement is representative:

> "I do not feel at liberty to attribute to Congress any * * * tautology. The statute first gives permission to sue a corporation in any district where it is incorporated or licensed or doing business. It then declares that such district shall be regarded as its residence. No one has suggested any reason for that declaration unless it was to give permission to the corporation to sue others in such district in addition to the previously given permission given to others to sue the corporation in any such district." Southern Paperboard Corporation v. United States, 127 F. Supp. 649, 650 (S.D. N.Y. 1955).

Professor Moore has found a meaning for the disputed words which does not comport with the above.

> "The language of the first clause of subsection (c) restricts the subsection to a corporation which 'may be sued.' And this restriction does not make superfluous the second, and concluding clause that 'such judicial district [in which the corporation is incorporated or licensed to do business or is doing business] shall be regarded as the residence of such corporation for venue purposes.' This clause serves a purpose in laying venue, in a transitory action, in a defendant's district where there are multiple defendants residing in different districts of the same state; and also in the case where defendants reside in different divisions of the same district or different districts in the same state. * * *" 1 Moore, Federal Practice 1503 (2d ed. 1963).

Nonetheless, Moore does not place his chief reliance on this interpretation in deciding that the statute defines residence for corporate defendants only. He emphasizes the fact that the Reviser's Note fails to indicate any intention to effect what would be a far-reaching change as to residence of corporate plaintiffs.

This position is seconded in the recent opinion, Robert E. Lee & Co. Inc. v. Veatch, 301 F.2d 434 (4 Cir. 1961) cert. den. 371 U.S. 813 (1962). There the court concluded that Congress would have designed a more sweeping language for Section 1391(c), such as using "all corporations" in the second clause "instead of the restrictive term 'such corporation'", if Congress had intended to do more than codify the rule of Neirbo Co. v. Bethlehem Shipbuilding Corp. Ltd., 308 U.S. 165 (1939), [that a corporation waives its venue privilege not to be sued in a state by obtaining a license to do business there].

Because of the well-balanced forces of reason on either side of this controversy a gentlemanly disagreement will no doubt continue among the courts and commentators until settled by Congress or the Supreme Court. This court is persuaded by those who argue that Congress did not intend the sweeping change which plaintiffs assert and that for purposes of 28 U.S.C. 1391(c) residence is defined only for corporate defendants. The court also holds that the residence of a corporation for purposes of 28 U.S.C. 1391(c) is defined in Section 1391(c). The twenty-six corporations which are not incorporated in Delaware are not properly before the court as plaintiffs in the present action.

II. The PMA and Standing to Sue

The next jurisdictional objection raised by the defendants concerns the standing to sue of the PMA. It is asserted that there is no actual controversy between PMA and the defendants. The regulations promulgated by the Commissioner do not apply to the Association; it neither manufactures nor distributes drugs and it has no occasion, therefore, to either label drug products or advertise them.

The PMA claims to be harmed in a strict dollars and cents fashion by the disputed regulations. The Association points out that under Article III of its by-laws membership dues are based on the annual business of its members. Rules which affect the income of its members therefore affect PMA.

It is not in its own right, however, but as the representative of some 140 drug companies that this court finds PMA to have standing to sue. In National Motor Freight Traffic Association, Inc. v. United States, certain associations of motor carriers sought to set aside a decision of the Interstate Commerce Commission. The Government argued that the plaintiffs lacked standing to sue because they were associations of carriers rather than the carriers actually affected by the contested order. The lower court agreed with the Government's contention holding that the associations were not qualified to sue because they suffered no legally cognizable injury "except in the remote sense that the problems of their members are their concern." National Motor Freight Traffic Association, Inc. v. United States, 205 F. Supp. 592, 593 (D.C. 1962), aff'd. 372 U.S. 246 (1963).

The Supreme Court specifically rejected this ground for decision:

> "The appellants are associations of motor carriers, authorized under 49 USC § 5b, and perform significant functions in the administration of the Interstate Commerce Act, including the representation of member carriers in proceedings before the Commission. Since individual member carriers of appellants will be aggrieved by the Commission's order, and since appellants are proper representatives of the interests of their members, appellants have standing to challenge the validity of the Commission's order in the District Court." National Motor Freight Traffic Association, Inc. v. United States, 372 U.S. 246, 247 (1963).

The defendants here make much of the Supreme Court's reference to the authorization of motor carrier associations

under 49 U. S. C. § 5b. That section, however, does no more than insulate associations approved by the I.C.C. from violation of the antitrust laws. The crux of the opinion centers on the association as a representative of members who are individually harmed. In that sense, the PMA is similar to the associations in the Motor Freight Traffic case. It represents its members before the Food and Drug administration just as the motor carrier associations appeared in their members' behalf before the I.C.C.

The PMA is a proper representative of the interests of its member drug companies and has standing to challenge the validity of the defendant Commissioner's regulations in this Court.

III. Propriety of a Judicial Determination at This Time

Next the defendants put forward two related arguments which go to the propriety of adjudication at this stage in the proceedings. First, they say that there is no actual controversy between the plaintiffs and defendants as required by the Declaratory Judgment Act, 28 U.S.C. § 2201.[4] Second, they maintain that regulations interpretive in nature, are reviewable only as they may later be called into question in an enforcement action and not upon their promulgation.

If a regulation is final and a justiciable controversy exists as to its legality, the regulation is ripe for review. A justiciable controversy arises where a plaintiff is confronted with substantial present or imminent harm. The regulations before the court are final and a justiciable controversy exists. The very presence of a threat of harm makes the regulations ready for review. Davis, Administrative Law Treatise, § 21.07.

[4]Plaintiffs also claim to be here under § 10 of the Administrative Procedure Act, 5 U.S.C.A. § 1009. Since the court finds that they are properly here for a declaratory judgment it is not necessary to discuss the procedure for review of administrative rule making.

Defendants say that plaintiffs should not be permitted a declaratory judgment but should have to await an enforcement proceeding before they can call the contested regulations into question. Plaintiffs may have judicial review of interpretive regulations upon their promulgation without awaiting some ultimate enforcement. Frozen Food Express v. United States, 351 U.S. 40 (1956); Federal Trade Commission v. Nash-Finch Company, 288 F. 2d 407 (D.C. Cir. 1961). They need not await an action which would only make the threat of harm more pressing. The possibility of harm is already apparent to this court. The regulations in issue have placed them in a dilemma. Either they must comply with the every time requirement and incur the costs of changing over their promotional material and labeling or they must follow their present course and risk prosecution. It is of no moment that the Attorney General and not the Food and Drug Administration may enforce these rules. Nor does it matter that the Attorney General has not yet threatened enforcement. Surely, the Commissioner does not announce regulations which he does not intend to enforce by any and every lawful means. From the plaintiffs' point of view danger is imminent. The regulations of which they complain are ripe for review. The declaratory judgment procedure is specifically suited for the determination of controversies where the plaintiffs must either comply with a contested regulation or continue their present course of conduct at their peril. To bar the courts to plaintiffs would be to do an injustice.

IV. The Attorney General as an Indispensable Party

The defendants next argue that the action cannot proceed because an indispensable party, the Attorney General, has not been joined. They point out that proceedings to enforce the Act or to restrain violations of the Act are to be brought in the name of the United States and that it is the Attorney General in his discretion who is granted authority to bring actions enforcing the Act.

Going back to first principles, indispensable parties are persons who have such an interest in a controversy that a final decree cannot be concluded without affecting that interest. 3 Moore, Federal Practice, 2150 (2d ed. 1963). It would seem unnecessarily cumbersome to hold that the Attorney General is such a party here. The decree sought here does not operate against the Attorney General except in a secondary fashion. He will not be forced to do anything no matter how the court decides. It is the defendants upon whom the benefit or blight of this decision will fall. The decree will expend itself on the defendants and not the Attorney General. The Attorney General is not a party indispensable to the instant litigation. See Federal Trade Commission v. Nash-Finch Company, supra.

V. The Present Controversy as an Unconsented Suit against the United States

Finally, defendants argue that this litigation is an unconsented suit against the United States.

They point out that the doctrine of sovereign immunity intervenes where the relief sought would interfere with the public administration or restrain the Government from acting or compel it to act. One of the cases cited in accord with this proposition is Larson v. Domestic and Foreign Commerce Corp., 337 U.S. 682 (1949). However, in Larson a significant exception is noted:

> "There may be, of course, suits for specific relief against officers of the sovereign which are not suits against the sovereign. * * * [W]here the officer's powers are limited by statute, his actions beyond those limitations are considered individual and not sovereign actions. The officer is not doing the business which the sovereign has empowered him to do or he is doing it in a way which the sovereign has forbidden. His actions are 'ultra vires' his authority and therefore may be made the object of specific relief. It is important to note that in such cases the relief can be

granted, without impleading the sovereign, only because of the officer's lack of delegated power." Larson v. Domestic and Foreign Commerce Corp., Ibid. at 689-90.

In their complaint plaintiffs assert:

> "20. These regulations are arbitrary and capricious and not in accordance with law, and constitute an unwarranted and unlawful directive to plaintiff companies in excess of the defendants statutory authority and short of statutory right, and contrary to the statutory provisions on which they purport to be based. * * *"

The relief plaintiffs seek is a declaration that the statutory provisions on which the contested regulations are based "do not impose, or authorize the defendants to impose" the requirements which the regulations embody.

This court does not regard plaintiffs' claim that defendants have acted outside the scope of their authority as frivolous. As the Larson case notes, a suit challenging the unauthorized actions of government officials is not a suit against the United States. This action may go forward in the absence of the United States consent to be sued. See, Philadelphia Company v. Stimson, 223 U.S. 605 (1912).

The decision of the merits of this case does not require as lengthy discussion as does negotiation of the procedural maze leading to the merits. The proposition is simple: Congress has enacted legislation setting out rules which must be complied with if a drug is to be properly branded. The Commissioner of Food and Drugs has issued regulations interpreting the Act of Congress. Plaintiffs attack these regulations.

Regulations of the type with which the court is here concerned are valid unless unreasonable or inconsistent with the statute. Davis, Administrative Law Treatise, § 5.05 (1958). The statute and the disputed regulation are here set out.

"Sec. 502. A drug or device shall be deemed to be misbranded—

* * *

"(e) (1) If it is a drug, unless (A) its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula), (i) the established name (as defined in subparagraph (2)) of the drug, if such there be, and (ii), in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient . . . and (B) for any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient: *Provided,* That to the extent that compliance with the requirements of clause (A) (ii) or clause (B) of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary."

* * *

"Section 1.104(g), 28 Fed. Reg. 6375 (June 20, 1963):

"§ 1.104 Drugs; statement of ingredients.

* * *

"(g) (1) If the label or labeling of a prescription drug bears a proprietary name or designation for the drug or any ingredient thereof, the established name, if such there be, corresponding to such proprietary name or designation, shall accompany each appearance of such proprietary name or designation. The established name shall be placed in direct conjunction with the proprietary name or designation, and the relationship between the proprietary name or designation and the established name shall be made clear by use of a phrase such as 'brand of,' preceding the established name, or by brackets surrounding the established name.

"(2) The established name shall be printed in letters that are at least half as large as the letters comprising the proprietary name or designation with which it is joined, and the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, layout, contrast, and other printing features."

It is clear from the legislative history that the chief concern of Congress in enacting § 502(e) was the prominent display on labeling of the generic name of a drug. Congress intended to put an end to the previous common practice whereby drug companies would mention the generic name of a drug in an inconspicuous place in microscopic print in order to enhance the value of their own trade name. Congress took pains to assure that the generic name would be printed in type large enough to be seen. This was accomplished by specifying that the generic name be printed in type at least half as large as that used for the trade name.

Not only was Congress concerned with the size of the display of the generic name, it was also concerned with the position of that display. To that end, Congress required that the generic name be placed "prominently" on labeling. This was the concern of Congress. It is necessarily the concern of the court.

Congress did not specify what it meant by prominent display. Would one mention of the generic name in juxtaposition with the first mention of the trade name suffice? In printed matter comprising several pages should the generic name be mentioned on each page at least once, perhaps at the top of the page? Congress laid down no guide lines.

The defendant Commissioner has interpreted the language of Congress with a broad sweep. He says that the generic name must appear at every mention of the trade name. His interpretation is inconsistent with the statute.

The very word which he has seized on to support the every time requirement belies the argument that Congress intended the generic name be used every time. If Congress had intended that the generic name appear every time the brand name appears there would be no reason to use the word "prominently". The use of the word shows Congress was concerned that the generic name appear in a conspicuous place. If the generic name appeared with every mention of the trade name the requirement of prominence would be unnecessary.

The defendants maintain that the legislative history indicates the adoption by Congress of the every time requirement. They rely heavily upon a statement by Senator Kefauver in which the Senator explained the Conference Committee's rejection of an amendment offered by Congressman O'Brien in the House. The O'Brien amendment would have required that the generic name appear "at the first place, and at the most conspicuous place if other than the first place, at which such proprietary name for such drug . . . is used. . . ." 108 Cong. Rec. 21081 (1962).

Kefauver explained,

> "This limitation was not accepted by the conferees. Thus the established name of a prescription drug must appear in type at least half as large as the trade name wherever the latter is used in drug promotional matter, including package inserts, and so forth." 108 Cong. Rec. 22039 (1962).

First, it is not clear that Kefauver's characterization of the O'Brien amendment as a limitation is accurate. Second, Kefauver's term "wherever" is not free from ambiguity. It could mean that the generic name must appear each time the trade name is mentioned. On the other hand, it could mean that the generic name must appear on a label or brochure or medicine box wherever the trade name is used. Apparently Kefauver favored the every time requirement. But nowhere

in the legislative history is there evidence to show that other members of the Congress favored the every time requirement or that they were aware that "prominently" should have a special meaning.

The views of Senator Kefauver, in this instance, cannot override what the court believes is the general Congressional intent. This is especially true since the expression of those views are circumscribed and open to doubt.

If Congress had meant that the generic name should appear with every mention of the trade name, it could have said so. It has not. It has said only that the generic name must appear prominently. The statute will not bear the interpretation which the defendants have put upon it.

Submit order in accordance herewith.

Wilmington, Delaware
April 30, 1964

APPENDIX D

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 15,055

ABBOTT LABORATORIES; ET AL.

vs.

ANTHONY J. CELEBREZZE, SECRETARY OF HEALTH, EDUCATION AND WELFARE, and GEORGE P. LARRICK, COMMISSIONER OF FOOD AND DRUGS, *Appellants*

(D.C. Civil No. 2737)

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

Present:

HASTIE and FREEDMAN, *Circuit Judges*, and WEBER, *District Judge*.

JUDGMENT

This cause came on to be heard on the record from the United States District Court for the District of Delaware and was argued by counsel.

On consideration whereof, it is now here ordered and adjudged by this Court that the judgment of the District Court, filed June 1, 1964, except as to paragraph five, be, and the same is hereby vacated, the injunction dissolved, and the cause remanded to the District Court with directions to dismiss the complaint in accordance with the opinion of this Court.

ATTEST:

IDA O. CRESKOFF
Clerk

November 1, 1965

APPENDIX E

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 15,054

ABBOTT LABORATORIES; ET AL.

vs.

ANTHONY J. CELEBREZZE, SECRETARY OF HEALTH, EDUCATION AND WELFARE, AND GEORGE P. LARRICK, COMMISSIONER OF FOOD AND DRUGS

ABBOTT LABORATORIES; ALCON LABORATORIES, INC.; ALLERGAN PHARMACEUTICALS; AMERICAN CYANAMID COMPANY; AMES COMPANY, INC.; BARNES-HIND PHARMACEUTICALS, INC.; BREWER & COMPANY, INC.; BURROUGHS WELLCOME & CO. (U. S. A.) INC.; CARTER PRODUCTS, INC.; HOFFMAN-LA ROCHE, INC.; HYNSON, WESTCOTT AND DUNNING INCORPORATED; JOHNSON & JOHNSON; ELI LILLY AND COMPANY; MALLINCKRODT CHEMICAL WORKS; THE S. E. MASSENGILL COMPANY; MEAD JOHNSON & COMPANY; MERCK & CO., INC.; THE NORWICH PHARMACAL COMPANY; OLIN MATHIESON CHEMICAL CORPORATION; ORGANON INC.; PARKE, DAVIS & COMPANY; A. H. ROBINS COMPANY, INCORPORATED; ROWELL LABORATORIES, INC.; SCHERING CORPORATION; SHERMAN LABORATORIES; SMITH KLINE & FRENCH LABORATORIES,

Appellants

(D.C. Civil No. 2737)

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE.

Present:

HASTIE and FREEDMAN, *Circuit Judges*, and WEBER, *District Judge*.

JUDGMENT

This cause came on to be heard on the record from the United States District Court for the District of Delaware and was argued by counsel.

On consideration whereof, it is now here ordered and adjudged by this Court that paragraph five of the judgment of the District Court, filed June 1, 1964, be and the same is hereby affirmed.

ATTEST:

IDA O. CRESKOFF
Clerk

November 1, 1965

APPENDIX F

FEDERAL FOOD, DRUG, AND COSMETIC ACT

Section 502(e)(1), 52 Stat. 1050 (1938), as amended by § 112(a) of the Drug Amendments of 1962, 76 Stat. 790, 21 U.S.C. § 352(e)(1):

"Sec. 502. A drug or device shall be deemed to be misbranded—

* * *

"(e)(1) If it is a drug, unless (A) its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula), (i) the established name (as defined in subparagraph (2)) of the drug, if such there be, and (ii), in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient . . . and (B) for any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient: *Provided,* That to the extent that compliance with the requirements of clause (A)(ii) or clause (B) of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary."

Section 502(n), added by § 131(a) of the Drug Amendments of 1962, 76 Stat. 791, 21 U.S.C. § 352(n):

"Sec. 502. A drug or device shall be deemed to be misbranded—

* * *

"(n) In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed

matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name as defined in section 502(e), printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under section 502(e), and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with the procedure specified in section 701(e) of this Act . . . ."

In the Supreme Court of the United States

OCTOBER TERM, 1965

No. 824

ABBOTT LABORATORIES, ET AL., PETITIONERS,

v.

ANTHONY J. CELEBREZZE, SECRETARY OF HEALTH, EDUCATION, AND WELFARE, AND GEORGE P. LARRICK, COMMISSIONER OF FOOD AND DRUGS.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a–9a) is reported at 352 F. 2d 286. The opinion of the district court (Pet. App. 12a–27a) is reported at 228 F. Supp. 855.

JURISDICTION

The judgments of the court of appeals were entered on November 1, 1965 (Pet. App. 28a–30a). The petition for a writ of certiorari was filed on December 15, 1965. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

207-060—66

QUESTIONS PRESENTED

1. Whether interpretive regulations issued by respondents with respect to the generic-name requirements of 1962 amendments to the Federal Food, Drug and Cosmetic Act may be challenged by petitioners in an action under the Declaratory Judgment Act or the Administrative Procedure Act.

2. Whether corporations doing business in a State but not incorporated therein may bring a civil suit in that State against federal officers under 28 U.S.C. 1391(e)(4).

STATUTES AND REGULATION INVOLVED

The relevant statutes and regulation appear in the Appendix, pp. 10–14, *infra*.

STATEMENT

Section 502(e)(1)(B) of the Federal Food, Drug and Cosmetic Act, enacted as part of the Drug Amendments of 1962, 76 Stat. 780, 790, requires "the established name" of any prescription drug to be "printed prominently" on any label and on any labeling in which any proprietary name of the drug appears "in type at least half as large as that used thereon for any proprietary name or designation for such drug" (p. 12, *infra*).[1] On February 14, 1963, the Commissioner of Food and Drugs, acting pursuant to rule-making authority of the Act, 21 U.S.C. 371(a), and under Section 4 of the Administrative

[1] Section 502(n) requires the established name to appear in any advertisement for a prescription drug in type at least half as large as that used for any trade or brand name. 76 Stat. 791–792 (p. 12, *infra*).

Procedure Act, 5 U.S.C. 1003, announced proposed regulations for the enforcement of this provision. The regulations provided that the generic name of a prescription drug accompany each appearance of any trade name on labels, labeling and advertising. 28 Fed. Reg. 1448. The Pharmaceutical Manufacturers Association (PMA) and several of its member firms offered written comments, challenging the proposed interpretation as legally erroneous. They asserted that the "every time" use of the established name would adversely affect the readability of the promotional material and asked that the interpretation not be adopted. No requests for exemption on the basis of a showing of impracticality were made. The regulations were adopted in final form on June 20, 1963. 28 Fed. Reg. 6375; App. pp. 13–14, *infra*.

In September 1963, the PMA and 37 of its 140 member companies instituted this action in the District Court for the District of Delaware under the Declaratory Judgment Act and the Administrative Procedure Act seeking a declaration that the "every time" interpretation embodied in the regulations was unwarranted and requesting an injunction against its enforcement. On cross-motions for summary judgment, the district court ruled that venue was improper for 26 corporate plaintiffs which were not incorporated in Delaware, but it otherwise granted the relief sought. The court held that the statute did not allow the interpretation made by the regulations and that the existence of the regulations posed a threat of harm to petitioners. It enjoined respondents from enforcing the interpretation embodied in the regula-

tions (Pet. App. 12a–27a). The court of appeals reversed on the ground that review of the interpretive regulation was not available at this juncture under the Declaratory Judgments Act or the Administrative Procedure Act (Pet. App. 1a–9a).

ARGUMENT

This case involves an attempt by petitioners to obtain a judicial determination regarding the validity of a regulation issued by respondents reflecting their understanding of a recently enacted statute. The court of appeals held that review of this "interpretive" regulation was not available at the present juncture (1) "in view of the policy of Congress limiting prior judicial review of administrative actions under [the Food, Drug and Cosmetics] Act to specific sections, not including the ones in question" and (2) "in view of the absence of an 'actual case or controversy' required for justiciability under the Declaratory Judgment Act" (Pet. App. 9a). Although we agree that there may be substance to petitioners' contention that the second reason given by the court of appeals is inconsistent with *Frozen Food Express* v. *United States*, 351 U.S. 40, we believe that the decision below is correct on the first ground—*i.e.*, that the provisions regarding judicial review in the Food, Drug and Cosmetic Act demonstrate Congress' intention to limit the instances in which the agency may be forced to defend its issued regulations prior to its enforcement of them. In light of the other available procedures by which the regulation's validity may be tested and the absence of any likelihood of criminal prosecution prior to a definitive decision regarding the regulation,

we believe there is no need for this Court presently to review the decision of the court of appeals.

1. As this Court observed in *Ewing v. Mytinger & Casselberry*, 339 U.S. 594, 600-601, Congress was "highly selective" in authorizing judicial review of administrative action under the Food, Drug, and Cosmetic Act. Section 701 of the Act, 21 U.S.C. 371, confers on the Secretary of Health, Education, and Welfare the authority to promulgate regulations, as do many other substantive provisions of the law. See, *e.g.*, 21 U.S.C. 352(n). Subsection (f) provides for judicial review only of "any order under subsection (e) of this section," and subsection (e) specifically enumerates seven kinds of regulations which are subject to the procedures prescribed therein (pp. 12-13, *infra*). The explicit listing of the enumerated regulations warrants the inference that Congress intended that no other regulations be reviewable before they were carried into effect by the agency.

The Act is enforced by administrative processes such as new-drug clearance or antibiotic certification as well as by injunction, seizure and criminal prosecution. Consequently, there are many avenues by which respondents' interpretation of the statute may be tested. Moreover, petitioners may seek exemption from the "every time" requirement under the proviso in Section 502(e)(1)(B). It is not the policy of the Food and Drug Administration to proceed in the first instance by way of criminal sanctions when, as the district court's decision discloses to be true here, its reading of the statute is subject to differences of opinion, and the Department of Justice will

not attempt to invoke criminal liability under the regulation at issue until its validity has been authoritatively established in administrative proceedings subject to judicial review or in civil proceedings. Consequently, there is no danger that fear of criminal prosecution will deter a test of the regulation's validity.[1]

Since enforcement of a regulation such as this one immediately presents a vehicle for judicial review of its validity, it was reasonable for Congress to make such a regulation non-reviewable at the present juncture. When it is actually enforced by refusal

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[1] Although the underlying merits of the controversy are not presently before the Court, we submit that the regulation, on its face, is a reasonable construction of the statute and is supported by its legislative history. The word "any" appears in Section 502(e)(1)(B) three times, and it is most reasonable to read it as meaning "all." See p. 12, *infra*. Thus read, the concluding phrase—"for any proprietary name or designation for such drug or ingredient"—means that the generic name must accompany *all* appearances of the brand-name on the label. This construction is supported by the legislative history of the 1962 amendments. The Senate Judiciary Committee's report stated with regard to this provision (Sen. Rep. No. 1744, pt. 2, 87th Cong., 2d Sess., p. 8):

> The substitute committee amendment * * * would require that the label bear the "established" name of the drug and the established name of each active ingredient * * *. It would also require that *on labels and on any labeling, wherever a trade or brand name is used, the established name*, as defined in this section, *must be shown in type at least one-half as large as that used for the trade or brand name.* [Emphasis added.]

The Conference Committee adopted the Senate version (H. Rep. No. 2426, 87th Cong., 2d Sess., pp. 23-24), and Senator Kefauver, the leading sponsor of the legislation, explained that it meant precisely what respondents' regulation says (108 Cong. Rec. 22039).

to clear a new drug which is, in respondents' view, misbranded, or by injunction or seizure, the reviewing court will have before it a concrete situation involving specific labeling. Petitioners' complaint alleged, *inter alia*, that the regulation was invalid because it rendered drug labeling "confusing and repetition and * * * difficult * * * to read," and this contention could obviously be weighed more intelligently in the context of a specific enforcement proceeding.

2. This Court held in *Frozen Food Express* v. *United States*, 351 U.S. 40, that a challenge to an interpretive order issued after a plenary administrative hearing presented a justiciable controversy which could be litigated in a reviewing court even before administrative enforcement. The present case turns, however, not only on justiciability but also on whether review at this juncture is authorized by statute. The governing statute in the *Frozen Food Express* case made "any order of the Interstate Commerce Commission" reviewable (28 U.S.C. 1336(a)) and did not, as does the Food, Drug and Cosmetic Act, narrowly define the kinds of regulations subject to judicial review. Similarly, in *United States* v. *Storer Broadcasting Co.*, 351 U.S. 192, a rule of the Federal Communications Commission was deemed reviewable in "light of the legislation allowing review of the Commission's actions." 351 U.S. at 200.[8]

[8] *Columbia Broadcasting System* v. *United States*, 316 U.S. 407, concerned a rule which had an immediate effect on station licensees who, if they followed the agency's regulation, were required to cancel existing affiliation agreements before the time at which the agency would implement its ruling.

Nor is review available here under the Administrative Procedure Act or the Declaratory Judgment Act. This is not a case, as was *Rusk* v. *Cort*, 369 U.S. 367, in which denial of relief under these statutes would compel the allegedly aggrieved party to undergo considerable hardship in order to obtain review.[4] Nor is it a case like *Leedom* v. *Kyne*, 358 U.S. 184, where this Court held an administrative agency's order reviewable notwithstanding the absence of any specific review authorization in the governing statute because "'absence of jurisdiction of the federal courts' would mean 'a sacrifice or obliteration of a right which Congress' has given" (358 U.S. at 190). In the present case an entire industry is seeking an adjudication regarding the intended enforcement of the Act by those who have the duty of enforcing it. Review of the validity of such enforcement will be available, with minimal hardship to petitioners, when enforcement is begun. The Administrative Procedure Act was not intended to authorize the anticipatory review sought here. See Attorney General's Manual on the Administrative Procedure Act, pp. 94–105.

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[4] In *Rusk* v. *Cort*, *supra*, this Court, though noting that the Administrative Procedure Act and the Declaratory Judgment Act appeared "clearly to permit an action such as was brought" in that case (369 U.S. at 372), went on to consider whether the statutorily prescribed procedures in the Immigration and Nationality Act were exclusive. The Court concluded that it was unlikely that Congress intended "that a native of this country living abroad must travel thousands of miles, be arrested, and go to jail in order to attack an administrative finding that he is not a citizen of the United States." 369 U.S. at 375.

3. Petitioners' second question is of no practical importance in this case. If, as the court of appeals held, the regulations are not presently reviewable, there is no court where this action could properly have been brought. On the other hand, if the decision of the district court is correct, that court's judgment will inure to the benefit of all the members of PMA, including those who did not join in the suit. And, in any event, if enforcement of the regulation is enjoined, there is no real likelihood that it will be enforced against companies who were not nominal plaintiffs in the suit.

CONCLUSION

For the reasons stated, it is respectfully submitted that the petition for a writ of certiorari should be denied.

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FEBRUARY 1966.

APPENDIX

The Federal Declaratory Judgment Act, 28 U.S.C. 2201, provides, in pertinent part:

Creation of remedy.

In a case of actual controversy within its jurisdiction, except with respect to Federal taxes, any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. * * *

Section 10 of the Administrative Procedure Act, 60 Stat. 243, 5 U.S.C. 1009, provides in pertinent part:

SEC. 10. Except so far as (1) statutes preclude judicial review or (2) agency action is by law committed to agency discretion—

(a) RIGHT OF REVIEW.—Any person suffering legal wrong because of any agency action, or adversely affected or aggrieved by such action within the meaning of any relevant statute, shall be entitled to judicial review thereof.

(b) FORM AND VENUE OF ACTION.—The form of proceeding for judicial review shall be any special statutory review proceeding relevant to the subject matter in any court specified by statute or, in the absence or inadequacy thereof, any applicable form of legal action (including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus) in any court of competent jurisdiction. Agency action shall be subject to judicial review in civil or criminal proceedings for judicial enforcement except to the extent that prior, adequate, and exclusive opportunity for such review is provided by law.

(c) REVIEWABLE ACTS.—Every agency action made reviewable by statute and every final agency action for which there is no other adequate remedy in any court shall be subject to judicial review. Any preliminary, procedural, or intermediate agency action or ruling not directly reviewable shall be subject to review upon the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final shall be final for the purposes of this subsection whether or not there has been presented or determined any application for a declaratory order, for any form of reconsideration, or (unless the agency otherwise requires by rule and provides that the action meanwhile shall be inoperative) for an appeal to superior agency authority.

28 U.S.C. 1391(e) provides, in pertinent part:

§ 1391. Venue generally.

* * * * *

(e) A civil action in which each defendant is an officer or employee of the United States or any agency thereof acting in his official capacity or under color of legal authority, or an agency of the United States, may, except as otherwise provided by law, be brought in any judicial district in which: (1) a defendant in the action resides, or (2) the cause of action arose, or (3) any real property involved in the action is situated, or (4) the plaintiff resides if no real property is involved in the action.

Section 502 of the Federal Food, Drug, and Cosmetic Act, 76 Stat. 780, 790, 21 U.S.C. 352, provides, in pertinent part:

SEC. 502. A drug or device shall be deemed to be misbranded—* * *

(e) * * *

(1) If it is a drug, unless * * *

(B) for any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling in which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient: *Provided*, That to the extent that compliance with the requirements of clause * * * (B) of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

* * * * * *

(n) In the case of any prescription drug * * * the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name as defined in section 502(e), printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula * * *, and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with the procedure specified in section 701(e) * * *

Section 701 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 371, provides, in pertinent part:

SEC. 701. Regulations and hearings.

(a) Authority to promulgate regulations.

The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary.

* * * * * *

(e) Procedure for establishment.

(1) Any action for the issuance, amendment, or repeal of any regulation under section 341, 343(j), 344(a), 346, 351(b), or 352 (d) or (h) of this title shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary, * * *

* * * * *

(f) Review of order.

(1) In a case of actual controversy as to the validity of any order under subsection (e) of this section, any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. * * *

* * * * *

21 C.F.R. 1.104 provides, in pertinent part:

* * * * *

(g)(1) If the label or labeling of a prescription drug bears a proprietary name or designation for the drug or any ingredient thereof, the established name, if such there be, corresponding to such proprietary name or designation, shall accompany each appearance of such proprietary name or designation. The established name shall be placed in direct conjunction with the proprietary name or designation, and the relationship between the proprietary name or designation and the established name shall be made clear by use of a phrase such as "brand of," preceding the established name, or by brackets surrounding the established name.

(2) The established name shall be printed in letters that are at least half as large as the

letters comprising the proprietary name or designation with which it is joined, and the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, layout, contrast, and other printing features.

U.S. GOVERNMENT PRINTING OFFICE:1966

No. [redacted] 39

Office-Supreme Court, U.S.
FILED
FEB 18 1966
JOHN F. DAVIS, CLERK

Supreme Court of the United States

OCTOBER TERM, 1965

ABBOTT LABORATORIES, ET AL., *Petitioners,*
v.
ANTHONY J. CELEBREZZE, Secretary of Health, Education and Welfare, and GEORGE P. LARRICK, Commissioner of Food and Drugs, *Respondents.*

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

PETITIONERS' REPLY BRIEF

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Supreme Court of the United States

OCTOBER TERM, 1965

No. 824

ABBOTT LABORATORIES, ET AL., *Petitioners,*

v.

ANTHONY J. CELEBREZZE, Secretary of Health, Education and Welfare, and GEORGE P. LARRICK, Commissioner of Food and Drugs, *Respondents.*

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

PETITIONERS' REPLY BRIEF

The central question presented by this Petition has been narrowed as a result of the Solicitor General's concessions and at the same time he has presented this Court with additional reasons for granting the writ.

1.

The issue now is whether either the Administrative Procedure Act or the Declaratory Judgment Act are available to seek review of Food and Drug Administration regulations prior to an actual enforcement proceeding.

The Court of Appeals' surprising determination, to which the Solicitor General lends his support, that Congress intended to preclude review of regulations of the type at issue here because it specified in Section 701(f) of the Food and Drug Act the availability of another type of judicial review for certain regulations is patently unsound. Even as

to regulations made reviewable under that section, the judicial review provisions of the Act are stated to be nonexclusive.[1] A fortiori, Congress did not intend the judicial review provisions of Section 701(f) to operate to preclude review under the Administrative Procedure Act or the Declaratory Judgment Act of regulations not covered by that section. Indeed, the legislative history of the Act makes it clear that Congress, in enacting the Food and Drug Act in 1938, intended only to provide an additional, nonexclusive method of obtaining review of certain regulations, and did not intend to preclude review under the Declaratory Judgment Act or general equity jurisdiction of any FDA regulation. As stated in the House Report on the 1938 legislation:

> "There is also saved as a method to review a regulation placed in effect by the Secretary whatever rights exist to initiate a historical proceeding in equity to enjoin the enforcement of the regulation, and whatever rights exist to initiate a declaratory judgment proceeding.
>
> "The special type of review above outlined, where the proceedings are instituted by the individual or business organization affected, will permit an early determination of the validity of the Secretary's action with respect to any proposal for a regulation, amendment, or repeal, and make for prompt certainty as to legal rights." H. R. Rep. No. 2139, 75th Cong., 3d Sess. 11 (1938).

Even absent this decisive legislative history, the Administrative Procedure Act, enacted in 1946, would nevertheless be available to challenge the regulations at issue here. This Court has required "clear and convincing evidence"

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[1] Section 701(f)(6) of the Act states that "the remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law."

of congressional intent to withhold review under the APA, *Rusk* v. *Cort*, 369 U. S. 367, 379-80 (1962), and has quoted with approval the statement in the House Report on the APA that "the mere failure to provide specially by statute for judicial review is certainly no evidence of intent to withhold review." *Heikkila* v. *Barber*, 345 U. S. 229, 232 (1953). In addition, the decision of the Court of Appeals on this point is inconsistent with the recent decision of the District of Columbia Circuit in *Elmo Division of Drive-X Co.* v. *Dixon*, 348 F. 2d 342, 343 (D. C. Cir. 1965), where that Court held with respect to the FTC that "statutory provisions concerning review of agency action by the Courts of Appeals do not in and of themselves . . . preclude District Court jurisdiction."

The question whether Congress precluded review of FDA regulations like those here involved should be decided by this Court. This issue is presented in every case where FDA regulations are challenged in declaratory judgment actions, including a case now pending in the Second Circuit. *Toilet Goods Ass'n* v. *Celebrezze*, 235 F. Supp. 648 (S. D. N. Y. 1964), on appeal, 2d Cir., No. 30261.

The issue, moreover, has far broader ramifications. The effect of the decision below would be that neither the Administrative Procedure Act nor the Declaratory Judgment Act would ever be available to review any order of any administrative agency where the agency's governing statute specifically authorizes the review of certain other orders. This proposition, on its face, is erroneous. In *Leedom* v. *Kyne*, 358 U. S. 184 (1958), for example, this Court held that the fact that certain types of NLRB orders were made reviewable in the Courts of Appeals did not by negative implication preclude equitable actions in a District Court to review other types of NLRB orders. Compare *United Gas Pipeline Co.* v. *FPC*, 181 F.2d 796 (D. C. Cir.), *cert. denied*, 340 U. S. 827 (1950), and *Arrow Airways, Inc.* v. *CAB*, 182 F. 2d 705 (D. C. Cir.), *cert. denied*, 340 U. S.

828 (1950), where the Court of Appeals held in each instance that orders of an administrative agency not reviewable in the Courts of Appeals under the judicial review provision applicable to the agency may be challenged in the District Courts under their general equity jurisdiction.

2.

The Solicitor General's concession (Br. Opp. 4) that "there may be substance to petitioners' contention" that the decision below is inconsistent with *Frozen Food Express* v. *United States,* 351 U. S. 40 (1956), should not be permitted to eliminate that issue from this case. While the Solicitor General concedes (Br. Opp. 7) that *Frozen Food Express* held that an "interpretive order"[2] can be challenged in advance of an enforcement proceeding, the fact of the matter is that the Government has in this and other litigation in the lower courts sought vigorously to narrow this decision to a point where it really will have no meaning. Respondents contended below that *Frozen Food Express* is applicable only where orders of the agency involved are made reviewable by specific statutory provisions dealing solely with that agency and asserted that this Court in *Frozen Food Express* did not contemplate review of interpretive orders under the Declaratory Judgment Act or the Administrative Procedure Act. This, it is submitted, flies in the face of the true meaning of the decision, and if certiorari is not granted here, the lower courts will still be open to arguments by respondents giving this decision a far too narrow effect.

The situation may be most graphically illustrated by the fact that respondents are relying on the Court of Appeals' decision in this very case to reinforce in other litigation this narrow and inappropriate view of justiciability, so plainly

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[2]The present order goes far beyond being "interpretive." It nowhere states that it purports to be merely the Secretary's "interpretation" of the statute. It *commands* petitioners to label their drugs in a particular way and states that a failure to do so would cause the drugs to be mislabeled.

inconsistent with *Frozen Food Express.* In a case now pending in the Second Circuit, *Toilet Goods Ass'n* v. *Celebrezze,* No. 30261, respondents are arguing—in contrast to the Solicitor General's concession as to the holding of *Frozen Food Express*—that "interpretive" regulations can never be challenged when they are promulgated and they cite for this proposition the Court of Appeals' decision below. (The Government's discussion in its brief before the Second Circuit in the *Toilet Goods Ass'n* case of the Court of Appeals' decision in this case is reprinted in the Appendix hereto.)[3]

In sum, we have a situation where the Solicitor General acknowledges that the Court of Appeals' holding on justiciability appears to be inconsistent with a decision of this Court, but where the Department of Justice continues in the lower courts to rely upon this erroneous holding. The decision of the Court of Appeals, contrary to this Court's decision in *Frozen Food Express,* that no justiciable controversy was presented should not be permitted to stand as an obstacle to obtaining prompt judicial determinations as to the validity of administrative regulations in this and other cases.

3.

Respondents strain to minimize the hardship to petitioners of having to act at their peril and await an enforcement proceeding before it can be determined whether the regulations are valid.[4] And, as if fear of criminal prosecu-

---

[3]It will be noted that the respondents' brief in the *Toilet Goods Ass'n* case cites in support of their position an article by Professor Davis. Professor Davis, however, has specifically approved the District Court's holding in that case that other regulations issued by the respondents can be challenged in a declaratory judgment action. 3 Davis, *Administrative Law* § 21.08, at 45 (Supp. 1965).

[4]Respondents also mention the provision in Section 502(e)(1)(B) for exemptions from the requirements of that section where compliance would be "impracticable". This provision, however, con-

tion were the only basis for this action, the Solicitor General now represents (Br. Opp. 5-6) that criminal prosecutions will not be brought under the regulations until their validity has been authoritatively determined.

Even on the assumption that the Government may be barred from bringing criminal proceedings by statements in a brief, it was admitted below that the regulations would be enforced. The regulations can still be enforced through seizure proceedings and injunction actions, and, in addition, respondents can attempt to enforce the regulations by preventing the initial marketing of drugs and antibiotics whose printed matter does not comply with the regulations. It is no "minimal hardship" (Br. Opp. 8) to subject individual petitioners to months of delay in securing approvals to market new and valuable drugs in order to obtain a judicial determination as to the validity of the regulations. Nor is it a "minimal hardship" to individual petitioners that their drugs be seized and kept off the market for failure to comply with the regulations. Seizure is a drastic sanction carrying opprobrium comparable to a criminal prosecution.

This Court has established that it is not necessary that there be a criminal sanction in order for administrative regulations to be reviewed. Thus, in both *Columbia Broadcasting System, Inc.* v. *United States*, 316 U. S. 407 (1942), and *United States* v. *Storer Broadcasting Co.*, 351 U. S. 192 (1956), regulations of the FCC were held to be reviewable even though the regulations at issue there were enforced only by administrative action; there was no provision for the institution of judicial proceedings to prosecute violators of the regulations. Here, too, even absent the

---

templates exemptions in individual situations, not where an entire industry challenges the legality of the "every time" requirement imposed by the respondents. In any event, the exemption provision applies only to one section of the regulations, that dealing with labeling, and does not apply to the section dealing with advertising, the legality of which was also challenged in this action (R. 14a, 66a; Pet. App. 3a).

possibility of criminal prosecution, petitioners are entitled to a determination of the regulations' validity in this declaratory judgment action in light of the other drastic sanctions available to the Government. In any event, it is quite clear that the Solicitor General's representation attempting to remove the threat of criminal prosecution at this stage of the proceeding—more than two years after the complaint was filed—cannot destroy the jurisdiction that the District Court had when the action was instituted. See *American Life Ins. Co.* v. *Stewart*, 300 U. S. 203, 215 (1937); *Spector Motor Service, Inc.* v. *O'Connor*, 340 U. S. 602, 605 (1951).

Petitioners should not be forced to the choice of either complying with regulations believed to be unlawful[5] or running the risk of suffering severe sanctions. Respondents should not be permitted to hold an entire industry at hazard, arbitrarily selecting both the companies against which these sanctions will be invoked and the drugs whose marketing will be delayed even if the regulations are ultimately held to be unlawful. There is simply no reason for not having, once and for all, a final determination in this declaratory judgment action of the validity of the regulations, an issue that was tendered below on cross motions for summary

[5]Since, as respondents acknowledge (Br. Opp. 6) "the underlying merits of the controversy are not presently before the Court," petitioners do not intend to show here why the regulations are invalid. It is sufficient to note the District Court's holding that the regulations are inconsistent with the statute and not supported by the legislative history of the 1962 Drug Amendments. (R. 54a-58a).

It should be emphasized, moreover, contrary to respondents' assertion (Br. Opp. 7), that petitioners did *not* urge that the regulations are invalid because they rendered printed material "confusing and repetitious . . . and difficult . . . to read." They alleged that the regulations were invalid because they were not authorized by the statute. The allegation quoted by respondents, which was never controverted, was among those directed to the injury that compliance with the regulations would cause petitioners. (R. 13a).

judgment presenting no disputed factual issues. No fact bearing on the respondents' power to issue the regulations will be any different in a later enforcement proceeding from what it is today.

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX

Brief Filed by the United States Attorney for the Southern District of New York, February 9, 1966, in *The Toilet Goods Ass'n, Inc., et al. v. Anthony J. Celebrezze, et al.*, United States Court of Appeals for the Second Circuit, Docket No. 30261, September Term, 1965.

"The significance of this distinction [between legislative and interpretative regulations] is accentuated by the recent decision of the Third Circuit in *Abbott Laboratories* v. *Celebrezze,* 352 F. 2d 286 (3rd Cir. 1965), a case strikingly similar to this dispute. There, as here, FDA issued certain regulations expressing its interpretation of new amendments to the Act. There, as here, the affected industry made no effort at compliance. There, as here, there was no effort by the Government to enforce the regulations. There, as here, the industry banded together to mount a massive assault on the regulations. There, as here, they sought a declaratory judgment and injunction. There, as here, they contended that appellants had plainly exceeded their statutory authority.

"The District Court in *Abbott* refused to dismiss the complaint and granted summary judgment voiding the regulations [228 F. Supp. 855 (D. Del. 1964)]. The District Court in this case relied heavily on that decision in its initial opinion (94a). However, the Court of Appeals reversed *Abbott* and dismissed the complaint for lack of a justiciable controversy. It recognized the patently interpretative nature of the regulations and the Congressional policy limiting prior judicial review of actions under the Food, Drug and Cosmetic Act. It found that the regulations in question did not have the force and effect of law; that they were not an 'adjudication,' 'order,' or 'licensing' under Section 2(d) of the Administrative Procedure Act [5 U. S. C. § 1001(d)] and, therefore, that they were not reviewable by declaratory judgment.

"The rationale of *Abbott Laboratories* applies with equal vigor to this case. The District Court here sought to distinguish *Abbott Laboratories* on the grounds that the regulation there at issue were [sic] interpretive as opposed to legislative (12a).* At the same time the District Court criticized such distinctions as 'hypertechnical' (9a). A plain reading of the statute discloses that FDA cannot issue 'legislative' regulations defining the scope of its regulatory authority. A plain reading of the regulations discloses that they are labelled as interpretative and fall within this classification by their very language. As such, they are not reviewable by declaratory judgment."

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*For a thorough discussion of the theoretical distinction between interpretative and legislative regulations see Davis, Administrative Rules—Interpretative, Legislative, & Retroactive, 57 Yale L. J. 919, 928-929 (1948).

SUPREME COURT, U. S.
FILED
AUG 25 1966
JOHN F. DAVIS, CLERK

No. 39

Supreme Court of the United States

OCTOBER TERM, 1966

ABBOTT LABORATORIES, ET AL., *Petitioners,*

v.

JOHN W. GARDNER, Secretary of Health, Education and Welfare, and JAMES L. GODDARD, Commissioner of Food and Drugs, *Respondents.*

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

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Supreme Court of the United States

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No. 39

ABBOTT LABORATORIES, ET AL., *Petitioners,*

v.

JOHN W. GARDNER, Secretary of Health, Education and Welfare, and JAMES L. GODDARD, Commissioner of Food and Drugs, *Respondents.*

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR PETITIONERS

This case is before the Court on writ of certiorari (383 U. S. 924) to review judgments of the United States Court of Appeals for the Third Circuit.

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Third Circuit in its case No. 15055 (R. 66-74) is reported at 352 F. 2d 286. The Court of Appeals' opinion in its case No. 15054 (R. 64-65) is reported at 352 F. 2d 524.

The opinion of the United States District Court for the District of Delaware (R. 41-55) is reported at 228 F. Supp. 855.

JURISDICTION

The judgments of the Court of Appeals were entered on November 1, 1965 (R. 65, 74-75). The petition for writ of certiorari was filed on December 15, 1965, and the petition was granted on February 28, 1966 (383 U. S. 924; R. 75). The jurisdiction of this Court is invoked under 28 U. S. C. § 1254(1).

STATUTES AND REGULATIONS INVOLVED

The pertinent provisions of the Declaratory Judgment Act (28 U. S. C. §§ 2201-02), Section 10 of the Administrative Procedure Act (60 Stat. 243 (1946), 5 U. S. C. § 1009), Section 1391 of the Judicial Code (28 U. S. C. § 1391), Sections 502(e), 502(n), and 701 of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1050, 1055 (1938), 76 Stat. 791 (1962), as amended, 21 U. S. C. §§ 352(e), 352(n), 371), and Sections 1.104(g) and 1.105(b) of the Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act (28 Fed. Reg. 6375, 6376 (1963), 21 C. F. R. §§ 1.104(g), 1.105(b)) are set forth in the Appendix to this Brief.

QUESTIONS PRESENTED

1. Whether a controversy appropriate for judicial determination, under the Declaratory Judgment Act and the Administrative Procedure Act, as to the validity of formal administrative regulations is presented on the complaint of companies subject to the regulations, (a) where compliance with the regulations will cause these companies grave and irreparable injury, (b) where noncompliance will render the companies subject to civil and criminal prosecutions, seizure proceedings, and harmful administrative actions, and (c) where the validity of the regulations presents a clear-cut issue of statutory construction admittedly without disputed factual questions.

2. Whether, under 28 U. S. C. § 1391(e), the statute recently enacted to liberalize venue requirements in actions against Federal officials, certain corporate petitioners are residents of and entitled to sue in a Federal District Court in a state other than the state of their incorporation.

STATEMENT

Proceedings below

Petitioners are thirty-seven companies that manufacture and distribute prescription drugs and the Pharmaceutical Manufacturers Association ("PMA"), an association of which these companies and other prescription drug companies are members (R. 4-7). Petitioners instituted this action in the United States District Court for the District of Delaware for a declaration that certain regulations issued by the respondents, the Secretary of Health, Education and Welfare and the Commissioner of Food and Drugs, are invalid and for an injunction against the regulations' enforcement (R. 16-17). The District Court's jurisdiction was invoked under Sections 1331 and 1337 of the Judicial Code, 28 U. S. C. §§ 1331, 1337, the Declaratory Judgment Act, and Section 10 of the Administrative Procedure Act (R. 4).

Respondents moved to dismiss on jurisdictional and procedural grounds and for summary judgment if the merits should be reached (R. 18-21). Petitioners filed a cross-motion for summary judgment (R. 22-23). The case was heard on these motions. No answer was filed. No affidavits were filed by the respondents disputing any of the factual allegations in the Complaint.

Of the thirty-eight petitioners, there were twelve—PMA, a Delaware nonprofit membership corporation, and eleven individual companies incorporated in Delaware (see R. 4-7)—as to which venue was not challenged and was

clearly proper. The District Court held that a justiciable controversy was presented and rejected other jurisdictional arguments which respondents interposed as obstacles to an adjudication on the merits. Having reached the merits, the District Court held the regulations invalid on the ground that they were inconsistent with the governing statute and enjoined enforcement of the regulations (R. 62-63).

Respondents appealed to the United States Court of Appeals for the Third Circuit (case No. 15055). The Court concluded that the District Court should have dismissed the action and reversed. It held that review of the regulations was not available "in view of the policy of Congress limiting prior judicial review of administrative actions under . . . [the Food, Drug, and Cosmetic] Act to specific sections, not including the ones in question, and in view of the absence of an 'actual case or controversy' required for justiciability under the Declaratory Judgment Act" (R. 74). The Court of Appeals did not deal with the question of the validity of the challenged regulations.

The District Court, while it reached the merits of the controversy and held the regulations invalid, had dismissed from the action those petitioners not incorporated in Delaware, holding that venue was not proper as to such petitioners. These petitioners appealed from this venue ruling, and in case No. 15054 the Court of Appeals affirmed this aspect of the District Court's decision.

The Court of Appeals has stayed the issuance of its mandate in both cases.

Nature and effect of the regulations

In 1962, the Federal Food, Drug, and Cosmetic Act was amended to provide, in Section 502(e)(1)(B), that a prescription drug is deemed "misbranded" unless the

"established name"[1] of the drug on the drug's label or labeling

> "is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug. . . ."

Section 502(n) of the Act, added in 1962, imposes the same requirement for advertisements of prescription drugs (Appendix, p. 4a).

On June 20, 1963, regulations relating to these statutory provisions were adopted by the respondents. The regulations were issued after a formal rule-making proceeding in accordance with Section 4 of the Administrative Procedure Act, 60 Stat. 238 (1946), 5 U. S. C. § 1003,[2] and were published in the Federal Register, 28 Fed. Reg. 6375. They were entitled "Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act." *Ibid.* They were made effective upon their publication. *Id.* at 6377.

Section 1.104(g) of the regulations, in contrast to the statutory requirement, ordered that the established name of a prescription drug "shall accompany each appearance" of that drug's proprietary or brand name on "labels"

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[1]The established name of a drug is defined in § 502(e)(2) of the Act, added by § 112(a) of the Drug Amendments of 1962, 76 Stat. 790, 21 U. S. C. § 352(e)(2). Under that section, the established name of a drug may be a "common or usual name," an "official title" used in an "official compendium," or an "official name" designated by the Secretary under § 508 of the Act, added by § 111(a) of the Drug Amendments of 1962, 76 Stat. 789, 21 U. S. C. § 358.

[2]Proposed regulations were published on February 14, 1963, 28 Fed. Reg. 1448. In response, the petitioning companies, either individually or through PMA, submitted comments contending, *inter alia*, that respondents could not lawfully impose the requirement contained in the proposed regulations that is the subject of this action (R. 13). Petitioners' contention was rejected by the respondents when the final regulations were issued.

and "labeling" for the drug. (Appendix, p. 7a). This same "every time" requirement was imposed for advertisements of prescription drugs by Section 1.105(b) of the regulations. (Appendix, p. 7a). These regulations were made applicable to advertisements and, by reason of the expansive definition of "label" and "labeling" in the Act,[8] to every piece of printed matter relating to a prescription drug—to "brochures, mailing pieces, detailing pieces, file cards, bulletins, price lists, catalogs, house organs, literature reprints, and similar pieces of printed matter." Section 1.105(l), 28 Fed. Reg. 6377, 21 C. F. R. § 1.105(l). The "every time" requirement imposed by the regulations applies both to one-page advertisements in medical journals and to books up to 100 pages or more which comprehensively set forth full information as to prescription drugs. It applies no matter how many times the brand name of a drug is mentioned in any single item or, indeed, on any single line or page. Each time the brand name of a drug appears on any of these items, the regulations require that its established name be printed in juxtaposition.

The regulations had a direct impact on each company involved in this litigation. In the regular course of business each company affixes labels to its prescription drugs and distributes labeling and advertising material in connection with these drugs (R. 8). Each company generally employs a proprietary (brand) name with respect to each prescription drug which it distributes, and these brand names appear on printed matter (including labels, labeling, and advertising) relating to the particular prescription drug

---

[8] "Label" is defined in § 201(k) of the Act, 52 Stat. 1041 (1938), 21 U. S. C. § 321(k), as "a display of written, printed, or graphic matter upon the immediate container of any article. . . ." Under § 201(m), "labeling" means "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

(R. 10). This printed matter is subject to the "every time" requirement imposed by the regulations.

Compliance with these mandatory regulations would require each company to cease the distribution of printed matter which did not contain an "every time" mention of the established name, to destroy such existing materials and to prepare new materials in their place that would be more difficult to read and comprehend and would in this and other ways injure the company's business (R. 15-16). Under Sections 302-04 of the Act, 52 Stat. 1043 (1938), as amended, 21 U. S. C. §§ 332-34, noncompliance with the regulations subjects each company to seizure proceedings, under which valuable drugs can be forfeited, and to criminal prosecutions and injunction proceedings (R. 11-12).[4] Respondents can also indirectly enforce the regulations by refusing to approve the marketing of "new drugs" under Section 505 of the Act, 52 Stat. 1052 (1938), as amended, 21 U. S. C. § 355, and by refusing to certify each batch of antibiotics under Section 507 of the Act, 59 Stat. 463 (1945), as amended, 21 U. S. C. § 357, unless related printed matter complies with the "every time" requirement (see R. 73-74).

During the course of argument in the District Court, it was made clear that respondents intended petitioners to comply with the regulations and that noncompliance would call into play the drastic enforcement provisions of the Act

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[4]Indeed, § 1.105(k) of the regulations, 28 Fed. Reg. 6377, 21 C. F. R. § 1.105(k), provides that any advertisement not in compliance with the "every time" requirement "shall cause stocks of such drug in possession of the person responsible for issuing or causing the issuance of the advertisement . . . to be misbranded under section 502(n) of the act." Sections 301(a) and (b) of the Act, 52 Stat. 1042 (1938), as amended, 21 U. S. C. §§ 331(a), (b), prohibit the "misbranding" of any drug and the introduction into commerce of any "misbranded" drug, and §§ 302-04 of the Act specify the sanctions for violating § 301.

(R. 25). These drastic remedies can be invoked—even though the drugs are perfectly safe and effective and even though the established name appears "prominently" on every page and no doctor or patient could be misled—solely on the ground that the established name does not appear every single time the proprietary name is used, as required by the regulations.

SUMMARY OF ARGUMENT

I

The regulations involved here affect the entire prescription drug industry. They were promulgated in 1963, more than three years ago, and petitioners promptly presented their claim that the regulations went beyond respondents' statutory authority for adjudication by the courts. That the claim has substance is clear from the fact that the District Court, the only court that has considered the question, held the regulations invalid. The Food and Drug Administration ("FDA") was itself on record that it welcomed resolution of this type of question by the courts. Yet in this proceeding, as in a case recently decided by the Court of Appeals for the Second Circuit, *Toilet Goods Ass'n* v. *Gardner*, 360 F. 2d 677,[8] respondents have made every conceivable effort to avoid decisions on the merits of controversies by the Federal courts.

The interests of all concerned—the FDA itself, the prescription drug industry, and the public—would be served by a definitive judicial determination as to the validity of the regulations. The Court of Appeals should have decided this question and should be directed to do so by this Court. There is no reason why petitioners should be required to violate the regulations, be prosecuted, and be prevented

[8] Petitions for writs of certiorari have been filed in this case. Nos. 336, 438, October Term, 1966.

from marketing new drugs and antibiotics before the validity of the regulations can be determined. Nor is there any possible justification for permitting respondents to hold an entire industry at hazard under the regulations by resisting an immediate straightforward test of their validity.

A clear-cut legal question of statutory construction was presented by the cross-motions for summary judgment. No facts were in dispute. No facts bearing on the validity of the regulations would be any different in a future enforcement proceeding from what they are today.

The regulations, once promulgated, were reviewable in this action instituted under the Declaratory Judgment Act and the Administrative Procedure Act. Adopted after a formal rule-making proceeding, they were published in the Federal Register and made effective upon their publication. They were represented to be "enforcement" regulations and were mandatory in nature—commanding that petitioners label and advertise their drugs in a certain way. In order to comply with the regulations, petitioners would have had to change their methods of doing business. On the other hand, noncompliance with the regulations would have exposed petitioners to drastic sanctions, including criminal penalties and seizure proceedings, as well as efforts by the respondents to prevent, through administrative action, the marketing of new and valuable drugs.

Under these circumstances, there was an "actual controversy," appropriate for judicial resolution, within the meaning of the Declaratory Judgment Act. That Act was designed to be available to relieve those subject to overreaching governmental action of the necessity of either complying with that action or suffering severe sanctions to test legality, the precise situation in which petitioners were put when the regulations were promulgated. By reason of the adverse impact of the regulations on petitioners, the regulations

were reviewable in this action, and it was not necessary that enforcement or penal proceedings be instituted before the legality of the regulations could be judicially determined. *Columbia Broadcasting System, Inc.* v. *United States*, 316 U. S. 407 (1942); *Frozen Food Express* v. *United States*, 351 U. S. 40 (1956); *United States* v. *Storer Broadcasting Co.*, 351 U. S. 192 (1956).

The regulations were also reviewable under Section 10 of the Administrative Procedure Act ("APA"). The District Court had jurisdiction over the subject matter of this action and in personam jurisdiction over the respondents, the regulations constituted "final agency action," and petitioners had suffered "legal wrong" as a consequence of that action. *United States* v. *Storer Broadcasting Co., supra.*

The Court of Appeals obviously erred in holding that the regulations were not ripe for review. The principles announced in the leading administrative law decisions of this Court, but ignored by the Court of Appeals, apply in determining the ripeness of regulations for review under the Declaratory Judgment Act and the APA. Under these decisions, it is clear that the regulations at issue here, whether or not characterized as "interpretive," were reviewable in this action. It is also clear that there is no requirement that there must be a specific and explicit threat of enforcement against a particular corporation before the legality of these formal, mandatory regulations can be judicially determined.

There is no basis for the conclusion that Congress intended to preclude judicial review of the regulations at issue here. There is no express preclusion of review in the statute. The mere fact that certain other types of regulations were made reviewable in a specific manner under the Food, Drug, and Cosmetic Act is no indication that Congress intended, as the Court of Appeals held, to preclude resort to traditional equitable and declaratory remedies in the

case of regulations of the type at issue here. See *Shields* v. *Utah Idaho Central R. R.*, 305 U. S. 177 (1938); *Stark* v. *Wickard*, 321 U. S. 288 (1944). There is lacking in this case "clear and convincing evidence" of congressional intent to preclude review. *Rusk* v. *Cort*, 369 U. S. 367 (1962); *Heikkila* v. *Barber*, 345 U. S. 229 (1953). On the contrary, the Act itself and its legislative history demonstrate the lack of any such congressional intent. Indeed, they show that Congress contemplated that traditional remedies would continue to be available to challenge any FDA action. The Act's judicial review provision, Section 701(f), is expressly stated to "be in addition to and not in substitution for any other remedies provided by law." The legislative history shows that Congress took note of the fact that these "other remedies provided by law" could include equity and declaratory judgment proceedings.

In short, the Declaratory Judgment Act and the judicial review provisions of the APA are applicable to the regulations at issue here, and the regulations were ripe for review under these statutes. The case should be remanded to the Court of Appeals for decision on the merits.

II

The Complaint was improperly dismissed as to those petitioners not incorporated in Delaware. Venue in this action against Federal officials is proper not only in the judicial district in which a corporation is incorporated, but also where it is licensed to do business or doing business. The contrary ruling below does not give proper scope to the definition of corporate residence in 28 U. S. C. § 1391(c) and is not in keeping with the purpose of 28 U. S. C. § 1391(e), the provision added in 1962 to liberalize the venue requirements applicable in actions against Federal

officials. While decision either way on this issue does not affect the outcome of this case, the issue should be resolved by the Court to clarify the meaning of these venue provisions and settle conflicting decisions in lower courts.

ARGUMENT

I

THE REGULATIONS ARE REVIEWABLE IN THIS ACTION

This action was brought by the prescription drug industry in order to be relieved of the burden of illegal regulations adopted by respondents. The alternative to this action—and a consequence of the Court of Appeals' decision if not reversed—would be individual enforcement proceedings against companies which do not comply with what the respondents have formally and finally announced as their interpretation of the statute. *Cf. National Van Lines, Inc.* v. *United States,* 326 F. 2d 362, 373 (7th Cir. 1964). This type of piecemeal litigation, binding only on the immediate parties to any particular action, would only serve to delay resolution of the basic question of whether the industry must comply with the regulations, a question whose prompt determination is in the public interest as well as in the interest of those subject to the regulations. Professor Jaffe is certainly correct when he observes:

> "The public has an interest in early implementation of policy; the regulated person has a legitimate interest whether to plan or not to plan his operation on the basis of a regulation." Jaffe, *Judicial Control of Administrative Action* 404 (1965).

The Food and Drug Administration itself has recognized the desirability of judicial proceedings instituted in good faith to challenge the legality of FDA regulations:

> "When any interested party feels that one of our regulations is wrong and should be challenged in the courts, we welcome such an action. Court decisions interpreting sections of the law or regulation that have given rise to honest differences of opinion are most helpful to us as guidelines to fair administration." Address of Commissioner of Food and Drugs George P. Larrick before the Pharmaceutical Manufacturers Association, April 14, 1964, p. 4.

From petitioners' standpoint, the desirability—indeed, the necessity—of obtaining a prompt determination of the regulations' validity is equally clear. Respondents did not controvert the adverse impact of the regulations on the petitioners. There is no dispute that compliance with the regulations requires petitioners to discontinue distributing the form of promotional material they have previously distributed, including such material now in their possession, and to substitute material they otherwise would not use. In effect, in order to comply, a change in petitioners' methods of doing business would be required. Nor is there any dispute that, under the statute, noncompliance with the regulations would render petitioners subject to criminal prosecutions, seizure actions, and injunction proceedings, as well as to administrative enforcement of the regulations through efforts to prevent the initial marketing of drugs and antibiotics whose printed matter does not comply with the regulations. As determined by the District Court:

> "The regulations in issue have placed them [petitioners] in a dilemma. Either they must comply with the every time requirement and incur the costs of changing over their promotional material and labeling or they must follow their present course and risk prosecution." (R. 49).

Finally, the issue of the regulations' validity is an issue that was particularly appropriate for resolution in this

action. It is a clear-cut legal issue of statutory construction. It was tendered on cross-motions for summary judgment presenting no disputed factual questions.

Under these circumstances, petitioners should not be forced to the choice of either complying with regulations believed to be unlawful—a belief shared by the District Court—or running the risk of suffering severe sanctions. Respondents should not be permitted to hold an entire industry at hazard, arbitrarily selecting the companies against which these sanctions will be invoked and the drugs whose marketing will be delayed. There is no reason for not having, once and for all, a final determination of the validity of the regulations in this action. There existed with respect to the regulations an "actual controversy," appropriate for judicial resolution, within the meaning of the Declaratory Judgment Act. In addition, the regulations constituted "final agency action" within the meaning of the APA, and declaratory and injunctive relief was appropriate under that Act.

The Court of Appeals, however, determined (1) that no justiciable controversy was presented and (2) that review of these regulations was not available under the Declaratory Judgment Act and the APA because only other types of FDA action are made expressly reviewable under the Food, Drug, and Cosmetic Act. Both of these grounds of the Court of Appeals' decision have been specifically rejected by the Second Circuit in a persuasive and well-reasoned opinion of Judge Friendly, *Toilet Goods Ass'n* v. *Gardner*, 360 F. 2d 677 (2d Cir. 1966). They should also be rejected by this Court. As the Second Circuit held with respect to the availability of the Declaratory Judgment Act and the APA:

> "We are not persuaded that by providing a procedure for review of certain administrative decisions under the Food and Drug Act in the courts of

> appeals, Congress meant to foreclose relief with respect to other agency action under the Administrative Procedure Act § 10, 5 U. S. C. § 1009, or the Declaratory Judgment Act, 28 U. S. C. § 2201, in a case where this would otherwise be appropriate. . . . Insofar as Abbott Labs. v. Celebrezze, 352 F. 2d 286, 289 (3 Cir. 1965), cert. granted, intimates otherwise, we are unwilling to follow it." 360 F. 2d at 683-84.

And, on the issue of justiciability:

> "Agreeing with the defendants that Abbott Labs. v. Celebrezze, 352 F. 2d 286 (3 Cir. 1965), cert. granted, is not distinguishable on any satisfying basis, we must confess, with all respect, our inability to understand why the plaintiffs there should be required to violate the challenged FDA regulation in order to raise the same legal issue as to which the district court had granted declaratory relief." 360 F. 2d at 686-87.

A. The Regulations Are Reviewable Under the Declaratory Judgment Act

At the outset, it deserves emphasis that a challenge to administrative regulations under the Declaratory Judgment Act is not a matter that is foreign to the purpose of that Act; the Act was specifically designed to be available not only in the area of private disputes but also in situations where the validity of governmental action is controverted. As explained in the 1934 Senate Judiciary Committee Report:

> "The [declaratory judgment] procedure has been especially useful in avoiding the necessity, now so often present, of having to act at one's peril or to act on one's own interpretation of his rights, or abandon one's rights because of a fear of incurring

damages. So now it is often necessary, in the absence of the declaratory judgment procedure, to violate or purport to violate a statute in order to obtain a judicial determination of its meaning or validity. Compare *Shredded Wheat Co.* v. *City of Elgin* (284 Ill. 389, 120 N. E. 248, 1918), where the parties were denied an injunction against the enforcement of a municipal ordinance carrying a penalty, and were advised to purport to violate the statute and then their rights could be determined, with *Erwin Billiard Parlor* v. *Buckner* (156 Tenn. 278, 300 S. W. 565, 1927), where a declaratory judgment under such circumstances was issued and settled the controversy.

* * *

"The Supreme Court mentioned one of its [declaratory judgment procedure] principal purposes in *Terrace* v. *Thompson* [263 U. S. 197, 216 (1923)] . . . : 'They are not obliged to take the risk of prosecution, fines, and imprisonment and loss of property in order to secure an adjudication of their rights.' " S. Rep. No. 1005, 73d Cong., 2d Sess. 2-3, 6 (1934).

Professor Borchard, the principal draftsman and proponent of the Declaratory Judgment Act and "a recognized authority on this subject,"[8] has stated:

"Possibly in no branch of litigation is the declaration more useful than in the relations between the citizen and the administration. With the growing complexity of government, . . . with ever widening

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[8]H. R. Rep. No. 2755, 74th Cong., 2d Sess. 8 (1936). As stated by this House Committee in reporting a previous version of the Food, Drug, and Cosmetic Act:

"The remedy furnished [by the Declaratory Judgment Act] seems to be peculiarly adapted to cases where the interests and rights of parties are affected by the acts of administrative officials." *Ibid.*

> powers vested in administrative boards and officials, the occasions for conflict and dispute are rapidly augmenting in frequency and importance. Yet the very fact that such disputes turn mainly upon questions of law, . . . makes this field of controversy peculiarly susceptible to the expeditious and pacifying ministrations of the declaratory judgment." Borchard, *Challenging 'Penal' Statutes by Declaratory Action*, 52 Yale L. J. 445 (1943).

Of course, in any particular situation the statutory requirement that there be an "actual controversy"—a requirement dictated by the constitutional "case or controversy" requirement[7]—must be satisfied. That this requirement was met in this case is shown by this Court's decisions in the landmark cases dealing with the ripeness of administrative regulations for review. *Columbia Broadcasting System, Inc.* v. *United States*, 316 U. S. 407 (1942); *Frozen Food Express* v. *United States*, 351 U. S. 40 (1956); and *United States* v. *Storer Broadcasting Co.*, 351 U. S. 192 (1956). These cases demonstrate that, because of the adverse impact of the regulations on petitioners, the regulations were reviewable in this action, and petitioners did not have to act at their peril and await the institution of penal or enforcement proceedings before the legality of the regulations could be judicially determined. *Toilet Goods Ass'n* v. *Gardner*, 360 F. 2d 677, 685-86 (2d Cir. 1966).

Columbia Broadcasting involved FCC regulations which provided that licenses would not thereafter be issued to stations having certain contractual relationships with networks. Although, as the Court noted, the regulations were not self-executing—they "did not operate of their own force to deny or cancel a license," 316 U. S. at 417—the

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[7] See Public Serv. Comm'n v. Wycoff Co., 344 U. S. 237, 242 (1952); United Pub. Workers v. Mitchell, 330 U. S. 75, 89, 93 (1947).

regulations were held to be ripe for review because of their adverse impact on CBS. The regulations purported to set a "standard of conduct," 316 U. S. at 418, and posed "the alternatives of compliance or severe penalties of forfeiture or disruption of business operations." *Toilet Goods Ass'n, supra*, 360 F. 2d at 685. As stated by this Court:

> "It is enough that failure to comply with them [the regulations] penalizes licensees, and appellant, with whom they contract. If an administrative order has that effect it is reviewable and it does not cease to be so merely because it is not certain whether the Commission will institute proceeding to enforce the penalty incurred under its regulations for non-compliance." 316 U. S. at 417-18.

The Court rejected an argument that the regulations were "no more subject to review than a press release similarly announcing . . . policy," 316 U. S. at 422, pointing out that the regulations were "avowedly adopted in the exercise of [rule-making] . . . power, [and were] couched in terms of command. . . ." *Ibid.* Although the validity of the regulations could have been determined in a licensing proceeding, the Court held that this was not the exclusive method of review:

> "Having adopted this order under its rule-making power, the Commission cannot insist that the appellant be relegated to that judicial review which would be exclusive if the rule-making power had never been exercised and consequently had never subjected appellant to the threatened irreparable injury." 316 U. S. at 421.

The *Storer* case also involved a licensing regulation of the FCC that was challenged upon its promulgation. The regulation was held ripe for review because the Commission exercised a power of rulemaking which controls

broadcasters" and the regulations "now operate to control the business affairs of Storer," 351 U. S. at 199, even though, as the dissent pointed out, the regulations could have been reviewed after they had been applied in a licensing proceeding. See 351 U. S. at 208.

In *Frozen Food Express*, this Court again focused on the practical impact of administrative action as the determinative factor in deciding whether such action is ripe for review. *Frozen Food Express* involved an interpretive report of the ICC in which it rendered its opinion as to the status of certain commodities under an exemption provided by the Interstate Commerce Act for the carriage of agricultural products by motor carriers. Over the contention that the report was not reviewable because it "has no operative effect," 351 U. S. at 46, this Court held that the report was reviewable because of its "immediate and practical impact on carriers":

> "The determination by the Commission that a commodity is not an exempt agricultural product has an immediate and practical impact on carriers who are transporting the commodities. . . . The 'order' of the Commission warns every carrier, who does not have authority from the Commission to transport those commodities, that it does so at the risk of incurring criminal penalties. . . . Where unauthorized operations occur, the Commission may proceed administratively and issue a cease and desist order. . . . The determination made by the Commission is not therefore abstract, theoretical, or academic. . . . The 'order' of the Commission . . . is, indeed, the basis for carriers in ordering and arranging their affairs. . . . The 'order' of the Commission is in substance a 'declaratory' one . . . which touches vital interests of carriers . . . and sets the standard for shaping the manner in which an important segment of the trucking business will be done." 351 U. S. at 43-44.

The instant case is "on all fours" with *Columbia Broadcasting, Storer,* and *Frozen Food Express.* Here, as in *Columbia Broadcasting,* an agency exercised its rule-making power to adopt formal, mandatory regulations—regulations "couched in terms of command," 316 U. S. at 422—which had an adverse impact on petitioners. Here, as in *Storer,* the promulgated regulations "operate to control the business affairs of" petitioners. 351 U. S. at 199. Finally, *Frozen Food Express* demonstrates that there is nothing abstract, theoretical, or academic about the controversy presented by the regulations at issue here. As in *Frozen Food Express,* the very existence of the regulations "has an immediate and practical impact on" petitioners. 351 U. S. at 44. Compliance with the regulations requires petitioners to change their method of doing business. On the other hand, noncompliance with the "every time" requirement imposed by the regulations subjects petitioners to the risk of criminal penalties, seizure proceedings, and injunction actions as well as to months of delay in securing the necessary approvals to market new and valuable drugs.[8] The holdings of this Court in these three cases show that an "actual controversy" is presented in this case.

[8] Petitioners recognize that, in the Brief in Opposition to the Petition for Certiorari in this case, the Solicitor General represented (pp. 5-6) that criminal prosecutions will not be brought under the regulations until their validity has been authoritatively determined. Even on the assumption, however, that the Government may be barred from bringing criminal proceedings by statements in a brief, the other severe sanctions which can be invoked for noncompliance with the regulations suffice to demonstrate their reviewability. See *Columbia Broadcasting* and *Storer* in which regulations were held reviewable even though there was no criminal sanction for their violation, and the regulations by their terms were enforceable only by administrative action. In any event, it is clear that the Solicitor General's representation—more than two years after the Complaint was filed—cannot operate to destroy the jurisdiction which the District Court had when the action was instituted or to sustain the Court of Appeals' erroneous dismissal of the action. See American Life Ins. Co. v. Stewart, 300 U. S. 203, 215 (1937); Spector Motor Service, Inc. v. O'Connor, 340 U. S. 602, 605 (1951).

B. The Regulations Are Reviewable Under the Administrative Procedure Act

This action was properly brought under Section 10 of the APA. Section 10 provides for judicial review of "final agency action" by any person suffering "legal wrong" as a result of such action. Section 10(b) contemplates that such review may be obtained through declaratory judgment and injunction actions, such as that brought here, instituted in a "court of competent jurisdiction." (Appendix, pp. 1a-2a).

First, there is no dispute that the District Court was a "court of competent jurisdiction." It had jurisdiction over the subject matter of this action under 28 U. S. C. §§ 1331, 1337 (*cf. Toilet Goods Ass'n* v. *Gardner*, 360 F. 2d 677, 679 (2d Cir. 1966), citing *Smith* v. *Kansas City Title & Trust Co.*, 255 U. S. 180 (1921)), and, through valid service of process under 28 U. S. C. § 1391(e), had acquired in personam jurisdiction over the respondents.

Second, it is also clear, despite the contrary implication in the Court of Appeals' opinion (R. 70), that the regulations fall within Section 10. The operative words are "final agency action." That the regulations constituted "agency action" is evident from the definitions contained in the APA itself,[9] and the *Storer* case demonstrates that the regulations had the requisite "finality." As has been discussed, *Storer* was a case in which regulations were challenged upon their promulgation and, although a specific statutory review provision was involved in that case, the

[9]Each respondent is an "agency" as that term is defined in § 2(a) of the APA, 5 U. S. C. § 1001(a). "Agency action" is defined in § 2(g), 5 U. S. C. § 1001(g), as including "every agency rule," and "rule" is defined in § 2(c), 5 U. S. C. § 1001(c), as "any agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy," a definition that clearly encompasses the regulations at issue in this proceeding.

action was also brought under the APA. See 351 U. S. at 195. The Court held that the regulations constituted "final agency action" within the meaning of the APA:

> "We think [Storer] . . . had standing to sue at the time it exercised its privilege. The process of rule-making was complete. It was final agency action, 5 U. S. C. § 1001(c) and (g): . . ." 351 U. S. at 198.

The regulations involved in this action were also formally promulgated after a completed rule-making proceeding and similarly constitute "final agency action."

Finally, that petitioners suffered "legal wrong" as a consequence of the regulations is also apparent. This requirement was explained as follows in *Storer*:

> "Legal wrong, as a ground for standing to appeal, was introduced by the Administrative Procedure Act. . . . In explanation the reports of the Senate, No. 752, 79th Cong., 1st Sess. 26, and the House, No. 1980, 79th Cong., 2d Sess. 42, define 'legal wrong':
>
> 'The phrase "legal wrong" means such a wrong as is specified in section 10(e). It means that something more than mere adverse personal effect must be shown in order to prevail—that is, that the adverse effect must be an illegal effect.'" 351 U. S. at 197 n. 6.

Section 10(e) of the APA, referred to by the Court, specifies the grounds upon which agency action can be invalidated, grounds specifically relied upon by the petitioners. (Compare Appendix, p. 2a, with R. 14.) In light of *Storer* and Section 10(e) of the APA, therefore, petitioners had suffered "legal wrong" since the "adverse effect" was caused by illegal action of the respondents. It has already been shown, p. 20, *supra*, that in terms of the "adverse effect" of the regulations upon petitioners, this case

is basically the same as *Storer* and the other administrative law decisions of this Court.

In sum, petitioners—persons suffering "legal wrong" as a consequence of the "final agency action" involved in this case—were entitled to review of that action under the Administrative Procedure Act. See *Rusk* v. *Cort*, 369 U. S. 367 (1962); *Brownell* v. *Tom We Shung*, 352 U. S. 180 (1956); *Shaughnessy* v. *Pedreiro*, 349 U. S. 48 (1955), in each of which this Court held that administrative action not reviewable under the statute pursuant to which the action was taken was reviewable under the APA through declaratory judgment and injunction actions.

C. The Court of Appeals Erred in Determining That No Justiciable Controversy Is Presented

What has already been said demonstrates that the Court of Appeals erred in holding that the regulations were not ripe for review. It is, however, appropriate to focus on three specific errors of the Court of Appeals: its refusal to follow the controlling decisions of this Court; its mistaken impression that "interpretive" regulations are ipso facto unreviewable; and its unwarranted assumption that there must be a specific and explicit threat of enforcement against a particular corporation before the validity of regulations may be judicially determined.

1. It ignored decisions of this Court

The Court of Appeals refused to follow *Frozen Food Express* and the other controlling decisions of this Court. Although it did not even mention the *Storer* case, the Court of Appeals sought to distinguish *Columbia Broadcasting* and *Frozen Food Express* on the ground that these cases arose under specific statutory review provisions and were not declaratory judgment actions (R. 69).[10] This distinction

[10] In fact, however, both *Frozen Food Express* and *Storer* were actions brought under the Administrative Procedure Act, as well as under the specific statutory provisions applicable to the ICC and FCC, respectively. See 351 U. S. at 42; 351 U. S. at 195.

has no bearing on the question of ripeness, as the Court of Appeals attempts to argue, for this Court has established that the rules governing justiciability are the same whether suit is brought under specific review provisions or the Declaratory Judgment Act.

Nukk v. *Shaughnessy*, 350 U. S. 869 (1955), *reversing per curiam* 125 F. Supp. 498 (S. D. N. Y. 1954), was a declaratory judgment action brought to challenge the validity of administrative regulations, the same type of action as that involved here. The District Court held, as did the Court of Appeals here, that the regulations were not ripe for review because there had been no specific threat to enforce the regulations. This Court reversed per curiam, saying only:

> "The Court is of opinion that the complaints do present a case and controversy. *Rochester Telephone Corp.* v. *United States*, 307 U. S. 125. The judgment is reversed and the case is remanded for consideration on the merits." 350 U. S. at 869.

Rochester Telephone, although an action brought under a specific statutory review provision, was thus held dispositive in a declaratory judgment action.

The *Nukk* case, in which this Court thought the appropriate decision so clear that it need not even write a full opinion, is of course in accord with decisions of the Court in which it has spelled out its reasoning. The results reached in *Columbia Broadcasting*, *Storer*, and *Frozen Food Express* show that a challenge to a regulation that has an adverse effect on private parties produces a "case or controversy" in the constitutional sense; otherwise, despite the statutory review provisions, each of those cases should have been dismissed for lack of jurisdiction. Since the require-

ment under the Declaratory Judgment Act that there be an "actual controversy" has the same meaning as the constitutional "case or controversy" requirement, see cases cited n. 7, *supra,* the Court of Appeals was clearly in error in holding that the leading administrative law decisions of this Court have no bearing on declaratory judgment actions brought to challenge administrative regulations.[11]

At the risk of belaboring the obvious, it should be pointed out that Professors Jaffe and Davis, two noted students of administrative law, have independently recognized the applicability to declaratory judgment actions of the principles announced in cases brought under specific review provisions. Jaffe, *Judicial Control of Administrative Action* 408 (1965); 3 Davis, *Administrative Law* § 21.06, at 150-51 (1958). In the words of Professor Davis:

> "In many cases, regulations of the ICC and of the FCC have been challenged by suits for injunctions

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[11]This Court's decisions in Ewing v. Mytinger & Casselberry, Inc., 339 U. S. 594 (1950), and Whitney Nat'l Bank v. Bank of New Orleans, 379 U. S. 411 (1965), relied on by the Court of Appeals (R. 70-71), do not affect the *Columbia Broadcasting* line of cases which govern this action. *Ewing* involved an attempt to review a finding of probable cause, not a final regulation. *Whitney Nat'l Bank* rested on the fact that the appropriate agency had never passed upon the contentions urged in the courts; here, petitioners' position as to the illegality of the "every time" requirement had been presented to and rejected by the respondents before this action was filed in the District Court. See n. 2, *supra.*

The Court of Appeals' reliance (R. 70) on the provision in § 502(e)(1)(B) for exemptions from the requirements of that section where compliance would be "impracticable" was also misplaced, for in *Storer* this Court held a regulation reviewable even though the FCC could waive its requirements. See 351 U. S. at 205. Furthermore, the exemption provision applies only to the section of the regulations dealing with labels and labeling and not to the section dealing with advertising, and, finally, petitioners' contention is that the regulations, whether or not compliance would be "practicable," are invalid.

under the Urgent Deficiencies Act; if a suit under that Act is not premature, no reason is apparent for holding premature an ordinary bill in equity or a declaratory action." *Ibid.* (Footnotes omitted.)

2. It sought to minimize the impact of the regulations by labeling them "interpretive"

The majority in *Frozen Food Express* rejected as a touchstone for reviewability the wholly separate question of whether regulations are "interpretive" or "legislative." The Court adopted a pragmatic, realistic approach, focusing on the impact of the regulation on those subject to its terms, and held that the ICC interpretive report involved in that case was ripe for review when it was issued. The Court of Appeals here, however, for some unexplained reason, chose to echo the *dissenting* opinion in *Frozen Food Express.* Compare R. 72 (the regulations do not have the force of law; "they rise no higher than the terms of the Act itself") with 351 U. S. at 46 (dissenting opinion) ("the order has no operative effect"; liability exists "because of a violation of the Act and not the order").

The Court of Appeals thus clearly erred. It is of no significance, as the Court thought, to label regulations "interpretive" (R. 69). As stated by the Court of Appeals for the Second Circuit in *Toilet Goods Ass'n, supra,* 360 F. 2d at 686:

> "[T]he interpretative character of a regulation does not necessarily make it unripe for review; we perceive no reason why a rule whereby an agency subjects to regulation activities contended to be immune should be exempt from immediate review because it purports to interpret a statute although it would not be if made in the exercise, contended to be illegal, of a substantive rule-making power. See Frozen Food Express v. United States . . .; Jaffe,

> Judicial Control of Administrative Action 405-07 (1965); and 1 Davis, Administrative Law Treatise § 5.03 (1965 Pocket Part), criticizing on this ground American President Lines, Ltd. v. FMC, 316 F. 2d 419 (D. C. Cir. 1963). . . ."

See also, *e.g.*, *FCC* v. *American Broadcasting Co.*, 347 U. S. 284 (1954) (immediate review of interpretive regulation); *Amshoff* v. *United States*, 228 F. 2d 261, 265 (7th Cir. 1955), *cert. denied*, 351 U. S. 939 (1956) (interpretive regulation is "final order" and reviewable under the Hobbs Act, 5 U. S. C. § 1032); *Lester C. Newton Trucking Co.* v. *United States*, 209 F. Supp. 600, 602 (D. Del. 1962), *aff'd per curiam*, 372 U. S. 702 (1963) ("interpretive opinion" of ICC held reviewable on authority of *Frozen Food Express*); *De Camp Bus Lines* v. *United States*, 224 F. Supp. 196, 201 (D. N. J. 1963) (order construing carriers' authority under certificate held reviewable). Compare *National Van Lines, Inc.* v. *United States*, 326 F. 2d 362 (7th Cir. 1964) (ICC report declaring that statute had been violated but not imposing sanctions held reviewable on authority of *Frozen Food Express*).

In short, the ripeness of a regulation for review does not depend upon what label is assigned to the regulation. However the regulations at issue here may be categorized, they were ripe for review because of their adverse impact on petitioners.

3. It improperly required a showing that specific enforcement of the regulations against a particular company was contemplated

The Court of Appeals' insistence that there be a specific threat of immediate prosecution (R. 72) is in clear conflict with *Columbia Broadcasting* in which, as noted, p. 18, *supra*, the Court held that regulations were ripe for review

even though it was not "certain" that any enforcement proceedings would be instituted. Nor is there any indication of any official threat of enforcement in *Storer* or *Frozen Food Express.*[12]

It may be that—as held in *Poe* v. *Ullman,* 367 U. S. 497, 508 (1961), with respect to a state statute challenged on constitutional grounds—if those subject to action taken by an administrative agency have no "realistic fear" that the action will be enforced, no justiciable controversy is presented as to the validity of that action. This, however, is clearly not the situation here where the administrative action consists of formally published and purportedly effective regulations, adopted after a rule-making proceeding, which purport to represent the agency's final and considered views, and where these views are stated in mandatory terms. Unless the respondents have been engaging in a purposeless intellectual exercise, how else can the regulations be explained except as incorporating a threat that drugs not complying with the regulations will be proceeded against?

The Complaint alleged that the respondents had a duty to enforce and cause enforcement of the statute in accordance with the regulations (R. 14). This allegation was never controverted. Indeed, respondents' counsel left no doubt during oral argument before the District Court that respondents intended petitioners to comply with the regu-

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[12]Even in cases in which the constitutionality of statutes is challenged in actions to enjoin their enforcement, there is no requirement that there be an official threat or other governmental enforcement action against any particular person who is subject to the statute. In neither Truax v. Raich, 239 U. S. 33 (1915), nor Pierce v. Society of Sisters, 268 U. S. 510 (1925), for example, had there been any such threat or enforcement action when suit was instituted; in each case the impact of the challenged statute upon the plaintiff, coupled with the statute's obvious viability, sufficed to present a justiciable controversy.

lations and that noncompliance would call into play the drastic enforcement provisions of the Act.[13] As the District Court observed, "Surely, the Commissioner does not announce regulations which he does not intend to enforce by any and every lawful means" (R. 49).

Two recent, well-reasoned Circuit Court decisions indicate that the formality of an agency regulation, adopted after notice and the opportunity for the submission of comments, is an important factor bearing on the appropriateness of passing on the validity of the regulation prior to its enforcement.[14] In *Toilet Goods Ass'n*, Judge Friendly, citing this Court's emphasis in *Columbia Broadcasting*, 316 U. S. at 422, and *Storer*, 351 U. S. at 198, on the fact that the agency involved had followed a formal rule-making procedure, stressed that "the Regulations under attack were issued after a full hearing with notice and by their terms represent the definitive agency position. . . ." 360 F. 2d at 685. The same is true of the regulations at issue here.

In addition, the Court of Appeals for the First Circuit, in an opinion by District Judge Caffrey, has stated with respect to the reviewability of a CAB order:

> "The question whether the Board's determination is appropriately reviewable at this point is es-

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[13] "The Court: Mr. Goodrich [counsel for respondents], when your department makes a regulation, I certainly hope that you intend for the drug industry to obey those regulations.

"Mr. Goodrich: We do indeed, sir.

"The Court: If not, you take whatever steps are necessary to enforce them.

"Mr. Goodrich: But the enforcement in the setting of a real case, where we have a piece of promotional material before us, is entirely different from an abstract question which is presented here." (R. 25; see also R. 34-35).

[14] Helco Prods. Co. v. McNutt, 137 F. 2d 681 (D. C. Cir. 1943), relied on heavily by the Court of Appeals here (R. 73), is clearly distinguishable. *Helco* involved an informal, unpublished letter of the FDA, not formal and purportedly final and effective regulations. See Jaffe, *Judicial Control of Administrative Action* 414-15 (1965).

> sentially one of the proper timing of judicial review and of whether this matter involves a sufficiently particularized controversy which is final in the sense that it is an at least firm (and perhaps binding) adoption of a position by the agency with regard to a course of conduct on the part of a member of the regulated industry which does not require further administrative action other than the possible imposition of sanctions. Among the factors to be considered are the relative formality of the agency's position, the degree of potential harm to the petitioner and the relative clarity of the issue presented for review." *Northeast Airlines, Inc.* v. *CAB*, 345 F. 2d 662, 664 (1st Cir. 1965).

The factors set forth by the First Circuit demonstrate the appropriateness of judicial review of the regulations at issue in this case. The regulations were formally adopted, they require a change in petitioners' method of doing business in order to avoid severe sanctions, and the issue presented is a clear-cut legal issue tendered on cross-motions for summary judgment, the basic facts being undisputed. The Court of Appeals' decision that no justiciable controversy was presented is in error.

D. The Court of Appeals Erred in Determining That the Act Precludes Review of the Regulations

Since, as has been shown, a justiciable controversy was presented as to the validity of the regulations, those who would prevent the courts from resolving this controversy must assume a heavy burden. There must be a clear demonstration that, although review would otherwise be proper under the Declaratory Judgment Act or the APA, the Congress intended that these statutes were not to be available to those harmed by this administrative action. There was no such demonstration in this case.

The Court of Appeals purported to find that Congress intended to preclude a judicial determination as to the legality of regulations of the type involved here prior to their enforcement. This determination as to the "intent of Congress" (R. 69, 70) was made even though nowhere in the Food, Drug, and Cosmetic Act is there any express preclusion of review and even though no legislative history was cited to support any such "intent." The Court of Appeals found this preclusionary "intent" solely by reason of the fact that regulations issued under certain sections of the Act, not including those under which the regulations involved here were issued, are made specifically reviewable under the special provisions of Section 701(f) of the Act.

It is clear that the Court of Appeals erred in determining, solely on this basis, that review of these regulations was precluded. First, the Act itself and its legislative history demonstrate that Congress contemplated that declaratory judgment and injunction proceedings would be available to challenge the legality of FDA actions. In addition, this clear congressional intent is in accord with the principles governing the basic question of the availability of judicial review.

1. Congress contemplated that traditional declaratory judgment and injunction remedies would be available to challenge FDA regulations

The Court of Appeals ignored the express declaration in Section 701(f)(6) of the Act that *"the remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law."* (Emphasis added). Thus, even as to regulations made reviewable under Section 701(f), the judicial review provisions of the Act are stated to be nonexclusive. It can hardly be said, as the Court of Appeals held, that these judicial review provisions—stated to be in addition to other available remedies—operate to preclude review of regulations not covered by these provisions.

As has been noted, the Court of Appeals for the Second Circuit has rejected the Third Circuit's determination in this case that Congress intended to foreclose relief under the APA and the Declaratory Judgment Act with respect to FDA action not made reviewable under Section 701(f)(1) of the Food, Drug, and Cosmetic Act. The Second Circuit, in an opinion by Judge Friendly, relied on the clear statement in Section 701(f)(6), quoted above, and, in addition, pointed to legislative history as indicating that Congress had no intention of limiting review of actions not made specifically reviewable under the Food, Drug, and Cosmetic Act. This legislative history demonstrates that the contrary view of the Third Circuit in this case cannot be supported. It confirms the nonexclusive nature of the judicial review provisions of the Act and shows that Congress recognized that traditional equitable remedies and declaratory judgments would be available to provide relief against any FDA action, where relief would otherwise be appropriate, despite the specific review provisions in Section 701(f) of the Act.

As reported by the House Interstate and Foreign Commerce Committee, Section 701 of the bill enacted as the Food and Drug Act of 1938 had the same structure that it has today.[15] Section 701(a) of the bill granted "the authority to promulgate regulations for the efficient enforcement of this Act." S. 5, 75th Cong., 3d Sess. (1938). Section 701(e) of the bill set forth the procedure to be followed in formulating regulations under certain specified

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[15]Because the bill as reported by the Conference Committee, and as enacted, was "substantially the same as" the bill as passed by the House, see H. R. Rep. No. 2716, 75th Cong., 3d Sess. 22 (1938), the House consideration of the judicial review provisions is particularly pertinent. There is nothing to indicate that the Senate had a different understanding as to the nonexclusive nature of these judicial review provisions.

sections of the Act. And, Section 701(f) of the bill provided for judicial review of "any order under subsection (e)" and specified that "the remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law." (Compare the corresponding provisions of the Act, printed in the Appendix hereto.)

The House Report states explicitly that the "other remedies provided by law" may include equity and declaratory judgment proceedings:

> "There is also saved as a method to review a regulation placed in effect by the Secretary whatever rights exist to initiate a historical proceeding in equity to enjoin the enforcement of the regulation and whatever rights exist to initiate a declaratory judgment proceeding." H. R. Rep. No. 2139, 75th Cong., 3d Sess. 11 (1938).[16]

The Report of the Committee minority was in accord. The minority stated that the method of review provided in Section 701(f)

> "is in addition to, and not in substitution for, other methods of review provided by law, such as equity proceedings and proceedings under the Declaratory Judgment Act." H. R. Rep. No. 2139, pt. 2, 75th Cong., 3d Sess. 1 (1938).

The minority went on to criticize the judicial review provisions as going beyond existing law and being unduly protective of industry. This criticism was also made in a

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[16]In connection with this statement in the House Report, it should be noted that in at least one case an injunction was issued against the enforcement of a regulation issued under the 1906 Food and Drug Act even though that Act contained no provision for judicial review of regulations. Morgan v. Nolan, 3 F. Supp. 143 (S. D. Ind. 1933), *aff'd*, 69 F. 2d 471 (7th Cir. 1934).

memorandum prepared by the Department of Justice which was made public during the House debate on the bill. The Justice Department objected to the judicial review provisions of the bill on the ground that they permitted suits in courts other than the District Court for the District of Columbia, the jurisdiction where, in the absence of any specific judicial review provision, actions would have to be instituted. The Justice Department then stated its legal conclusion:

> "[T]he entire subsection [701(f)] is really unnecessary, because even without any express provision in the bill for court review, any citizen aggrieved by any order of the Secretary, who contends that the order is invalid, may test the legality of the order by bringing an injunction suit against the Secretary, or the head of the Bureau, under the general equity powers of the court." 83 Cong. Rec. 7892 (1938).[17]

[17]This same point—that judicial review was available even absent a specific provision for judicial review in the Act—was made strongly in a House Report during a previous Congress. The House Committee had deleted from a Senate-passed bill a provision for judicial review of regulations because the Committee felt that the existing judicial remedies were sufficient. In language particularly apposite to the issue involved here, the Committee explained:

> "The committee felt that there was no reason to add to the existing remedies which are applicable in the case of administrative action under the many other acts passed by Congress. There is always an appropriate remedy in equity in cases where an administrative officer has exceeded his authority and there is no adequate remedy of law, and furthermore the committee is of the opinion that ample protection is given by the so-called Declaratory Judgments Act enacted on June 14, 1934. . . . Insofar as the court would, under the Senate bill, have been empowered to give relief in case a regulation or an act of the Secretary was unreasonable, arbitrary, or capricious, or not in accordance with law, this is merely the ordinary principle which the court applies in cases where an administrative official has exceeded his authority, and a person affected by an administrative official's action may always, whether in a criminal proceeding, equity proceeding, or any other proceeding, raise these issues. . . .

Representative Mapes offered an amendment to Section 701(f) which, among other things, would have authorized review in the Courts of Appeals instead of in the District Courts. See 83 Cong. Rec. 7891 (1938). Representative Mapes echoed the views of the Department of Justice:

> "[U]nder existing law any individual may go into the district court in which he resides for the purpose of obtaining an injunction against any order of the Food and Drug Administration that applies to him, that is arbitrary, capricious, unreasonable, or contrary to law, and that will cause him irreparable damage. *No one proposes to take that right away from anyone.*" *Id.* at 7893. (Emphasis added.)

He was questioned by Representative Voorhis:

> "MR. VOORHIS. What about injunctions under the gentleman's amendment?
> "MR. MAPES. The injunction matter is outside of both of these provisions. *The injunction remedy by any aggrieved person is had without reference to the provisions in the bill or to my amendment.*" *Id.* at 7894. (Emphasis added.)

Although Representative Mapes' amendment was defeated, *id.* at 7898, a provision for review in the Court of Appeals was contained in the bill as reported by the Conference Committee and as enacted. The Conference Committee specifically noted that

> "the provision of the House amendment under which the remedies provided for are in addition to, and not in substitution for, other legal remedies, is

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The remedy furnished [by the Declaratory Judgment Act] seems to be peculiarly adapted to cases where the interests and rights of parties are affected by the acts of administrative officials. Prof. Edwin Borchard, of the Yale University School of Law, a recognized authority on this subject, stated in an article appearing in the Law Week that it is in this field that the act will have its greatest usefulness." H. R. Rep. No. 2755, 74th Cong., 2d Sess. 8-9 (1936).

retained." H. R. Rep. No. 2716, 75th Cong., 3d Sess. 25 (1938).

The legislative history thus conclusively demonstrates that Congress specifically contemplated that traditional remedies would be available to challenge any FDA action. The provision for judicial review of certain specified regulations was intended to constitute an additional remedy in the case of the specified regulations—regulations dealing with technical and scientific issues, and to be adopted after evidentiary hearings—and is not an implied preclusion of the review of other FDA action. The Declaratory Judgment Act and the APA are available to review the regulations at issue here and, as has been shown, the requirements of those statutes were met in this case. The Court of Appeals' decision barring the courts to petitioners was in error and contrary to the intent of Congress.

2. This clear congressional intent is consistent with the principles governing the availability of judicial review

The Court of Appeals did not even mention the express declaration in Section 701(f)(6) of the Act that the judicial review provisions of the Act are nonexclusive. Nor did the Court refer at all to any legislative history as bearing on the availability of judicial review. The Court held baldly that review of the regulations at issue here was precluded solely because other action taken by the Food and Drug Administration is made specifically reviewable under the Food and Drug Act. This holding is demonstrably erroneous in light of the clear and unambiguous legislative history which has already been discussed. Moreover, this ruling of the Court of Appeals is in clear conflict with decisions of this Court. These decisions, even prior to the enactment of the Administrative Procedure Act, demonstrate that the mere fact that certain agency action is made specif-

ically reviewable does not preclude, by negative implication, the reviewability of other action. *Shields* v. *Utah Idaho Central R. R.*, 305 U. S. 177 (1938); *Stark* v. *Wickard*, 321 U. S. 288 (1944). With the enactment of the APA, it is untenable even to argue, as the Court of Appeals held, that review of the regulations at issue here is unavailable solely because other regulations are made specifically reviewable.

Shields involved an Interstate Commerce Commission determination that the railroad was not exempt from the requirements of the Railway Labor Act. The Court had previously held in *Shannahan* v. *United States*, 303 U. S. 596 (1938), that such a determination was not an "order" reviewable under the Urgent Deficiencies Act. The Court held in *Shields*, however, that the determination was reviewable under the general equity jurisdiction of the District Courts. In other words, the fact that certain ICC action was reviewable under the Urgent Deficiencies Act did not by negative implication preclude review of other action under general equity jurisdiction.

Stark v. *Wickard* was an action brought by milk producers to enjoin the implementation of certain provisions of an order of the Secretary of Agriculture issued under the Agricultural Marketing Agreement Act. The Act provided for review of other orders and made no provision for review of the type of order there involved. The Court nevertheless held—over the objection of Mr. Justice Frankfurter in dissent that the specific provision for review of some orders demonstrated that other orders were not reviewable (321 U. S. at 318-19)—that the order was reviewable under the general equity jurisdiction of the District Courts. Indeed, the Court, after noting that provision was made in the Act for the review of some orders, stated:

> "With this recognition by Congress of the applicability of judicial review in this field, it is not to be

> lightly assumed that the silence of the statute bars from the courts an otherwise justiciable issue. . . ." 321 U. S. at 309.

There can be no doubt that the *Shields* and *Stark* v. *Wickard* approach was confirmed and strengthened with the enactment of the Administrative Procedure Act in 1946. This Court has referred to "the generous review provisions" of the APA and has stated that they granted "an expanded right of review" and that the APA "is to be given a 'hospitable' interpretation." *Shaughnessy* v. *Pedreiro*, 349 U. S. 48, 51 (1955); see *Brownell* v. *Tom We Shung*, 352 U. S. 180, 185 (1956). In light of the "broadly remedial provisions" of the APA, the Court has stressed that it will require "clear and convincing evidence" of congressional intent before it will hold that judicial review of administrative action is unavailable. *Rusk* v. *Cort*, 369 U. S. 367, 379-80 (1962). *Heikkila* v. *Barber*, 345 U. S. 229 (1953), in which this Court reviewed the legislative history of the APA, shows that in this case the mere fact that some FDA regulations were made specifically reviewable is not "clear and convincing evidence" of congressional intent to preclude review of other regulations. In *Heikkila* the Court quoted with approval the statement in the House Report on the APA:

> " 'To preclude judicial review under this bill a statute, if not specific in withholding such review, must upon its face give clear and convincing evidence of an intent to withhold it. The mere failure to provide specially by statute for judicial review is certainly no evidence of intent to withhold review.' " 345 U. S. at 232.

The Court indicated the necessity for a close examination of the purpose and history as well as the text of a statute in order to determine whether Congress intended to prevent the courts from affording relief to those adversely affected

by administrative action. The text of a statute, even where it looks toward the unavailability of review, is not decisive:

> "Mere failure to provide for judicial intervention is not conclusive; neither is the presence of language which appears to bar it." 345 U. S. at 233, citing, *inter alia*, *Stark* v. *Wickard*.

The Court of Appeals here, however,—with an extremely superficial examination of the text of the statute and with no consideration of its purpose or legislative history—held that Congress intended, by implication, to preclude review of the type of regulations involved in this case because it specified the availability of review for other regulations. If this implication is supportable on this basis in this case, it necessarily means that no order of any administrative agency is reviewable under the Declaratory Judgment Act and the APA where the agency's governing statute specifically authorizes the review of certain other orders. This cannot be, and is not, correct. The Court of Appeals' decision cannot square with *Shields* and *Stark* v. *Wickard;* it is also contrary to, *e.g.*, *Leedom* v. *Kyne,* 358 U. S. 184 (1958) (that certain types of NLRB orders were made reviewable in the Courts of Appeals did not by negative implication preclude equitable District Court action to review other types of NLRB orders), and *Rusk* v. *Cort, supra* (statutory authorization of review by certain class of persons did not by negative implication preclude review by other persons). See also, *e.g.*, *Elmo Division of Drive-X Co.* v. *Dixon,* 348 F. 2d 342, 343 (D. C. Cir. 1965); *Deering Milliken, Inc.* v. *Johnston,* 295 F. 2d 856 (4th Cir. 1961). As pointed out by Professor Jaffe:

> "The mere fact that some acts are made reviewable should not suffice to support an implication of exclusion as to others. The right to review is too impor-

tant to be excluded on such slender and indeterminate evidence of legislative intent." Jaffe, *Judicial Control of Administrative Action* 357 (1965).

II

PETITIONERS NOT INCORPORATED IN DELAWARE ARE PROPERLY PARTIES PLAINTIFF ALONG WITH PETITIONERS INCORPORATED IN DELAWARE AS TO WHOM VENUE IS ADMITTEDLY PROPER

In this proceeding involving a basic question of importance to the entire prescription drug industry, suit was instituted by thirty-seven representative manufacturers and by the Pharmaceutical Manufacturers Association ("PMA"), the association of which these companies and more than 100 other prescription drug manufacturers are members. Venue in the District Court for the District of Delaware was admittedly proper under the governing venue provision, 28 U. S. C. § 1391(e)(4) (Appendix, p. 3a), for the twelve petitioners, including the PMA, incorporated in Delaware. Consequently, the basic issue of these petitioners' right to an adjudication of the legality of the regulations is before this Court, regardless of the disposition of the venue issue involving other plaintiffs not incorporated in Delaware.

The venue question as to petitioners not incorporated in Delaware was decided by the Court of Appeals in case No. 15054 and was taken by this Court under its grant of certiorari. A basic question of considerable importance to the administration of justice in the lower Federal courts is involved. It plainly merits resolution by this Court now. The restrictive holdings below contravene the purpose of the liberalizing venue provision and would preclude plaintiffs with a proper interest from being parties in litigation affecting their rights.

Under the venue statute applicable to this action, 28 U. S. C. § 1391(e)(4), venue is properly laid "in any judicial district in which . . . the plaintiff resides. . . ." There is no dispute that, under this section, a corporate plaintiff "resides" at least in its state of incorporation. The District Court determined that a corporate plaintiff "resides" only in its state of incorporation (R. 43-46), and the Court of Appeals in its case No. 15054 affirmed the District Court's dismissal of the Complaint as to those petitioners not incorporated in Delaware (R. 64-65).

Petitioners believe that the provisions of Section 1391 and the congressional purpose in broadening this section, and in particular in amending this section in 1962 to add subsection (e)(4) which controls this action, show that venue was also proper for those petitioners not incorporated in Delaware and that the contrary conclusion by the courts below was in error.

A. Prior to the codification of the Judicial Code in 1948, for venue purposes a corporation was deemed a resident only of its state of incorporation. *E.g., Suttle* v. *Reich Bros. Constr. Co.*, 333 U. S. 163 (1948). This was changed in 1948 by the adoption of Section 1391(c) of the Judicial Code, which reads:

> "A corporation may be sued in any judicial district in which it is incorporated or licensed to do business or is doing business, *and such judicial district shall be regarded as the residence of such corporation for venue purposes.*" (Emphasis added.)

Under this section, it is clear that a corporate defendant now "resides" in every district in which it is either incorporated, licensed to do business, or doing business. The issue is whether this section redefined corporate residence for corporate plaintiffs as well as for corporate defendants.

Section 1391(a) provides that an action in which Federal jurisdiction is based solely on diversity of citizenship

may be brought in the judicial district in which either the plaintiffs or the defendants "reside." In this situation, a conflict soon developed among the courts and the commentators as to whether the definition of corporate residence in Section 1391(c) applied where venue was sought to be based on the residence of corporate plaintiffs. The conflicting cases and commentary are cited in the District Court's opinion (R. 44 nn. 2, 3).

The fact that this conflict developed certainly demonstrates that the statutory language can be read either way—as limited to corporate defendants or as encompassing corporate plaintiffs as well. Nor is the Reviser's Note to this section of any help. See 1 Moore, *Federal Practice* ¶ 0.142[5.-3], at 1489 n. 1 (1964). There is, thus, no authoritative source which can be looked to for the answer. Petitioners urge that this Court follow the reasoning of those courts which have held that Section 1391(c) applies to corporate plaintiffs as well as corporate defendants. This reasoning is spelled out by Judge Ryan in *Freiday* v. *Coudin*, 83 F. Supp. 516, 517-18 (S. D. N. Y.), *appeal dismissed by consent*, 177 F. 2d 1020 (2d Cir. 1949):

> "To give full effect to the words 'and such judicial district shall be regarded as the residence of such corporation for venue purposes' one must conclude that they refer to both plaintiff and defendant corporations. To conclude otherwise one would have to attribute to Congress the anomalous intent to define the residence of corporate defendants but not that of corporate plaintiffs. Under such interpretation, there would be nothing in the Code defining the residence of corporate plaintiffs. . . . Furthermore, corporations would be amenable to suit in jurisdictions in which they were licensed to do business or were doing business, but they could not sue as plaintiffs [under 28 U. S. C. § 1391(a)] in those very same districts unless all defendants were residents of that district."

It has not been suggested that the result reached in cases consistent with *Freiday* v. *Cowdin* is in any way undesirable or without logical support. See 1 Moore, *supra* at 1503. After all, a liberal reading of Section 1391(c) in diversity cases—the situation in which the issue is presented—is indicated by the fact that such cases are already governed by a more liberal venue requirement than are "Federal question" cases.[18] Nor can there be any legitimate fear, in view of the necessity for service of process on the defendant, that the reading of Section 1391(c) urged by petitioners would in any way prejudice the defendants in actions brought by corporate plaintiffs.

The District Court here, however, rejected the reasoning of *Freiday* v. *Cowdin* and its companion cases, and the Court of Appeals affirmed per curiam. The District Court, relying on Professor Moore, advanced two reasons for its action, neither of which, it is believed, affects the persuasiveness of the *Freiday* v. *Cowdin* reasoning. First, the District Court noted that Professor Moore had concluded that effect could be given to the second clause of Section 1391(c) even if that clause were not held applicable to corporate plaintiffs.[19] This must, however, be conceded to be a very limited and technical effect; as Chief Judge Ryan stated in *Freiday* v. *Cowdin, supra,* "to give *full effect* to the words [of the second clause of Section 1391(c)] one must conclude that they refer to both plaintiff and defendant corporations." (Emphasis added.) Second, the District Court was im-

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[18] Under § 1391(a), in diversity cases venue is based on either the plaintiff's or the defendant's residence; in "Federal question" cases venue is proper under § 1391(b) only in the district in which the defendant resides.

[19] Professor Moore states:

> "This [second] clause serves a purpose in laying venue, in a transitory action, in a defendant's district where there are multiple defendants residing in different districts of the same state; and also in the case where defendants reside in different divisions of the same district or different districts in the same state." 1 Moore, *supra* at 1503.

pressed by the argument that Congress did not intend to effect what the Court concluded would be a "far-reaching change" (R. 46) were Section 1391(c) applicable to corporate plaintiffs.[20] Even Professor Moore, however, does not believe that this argument carries much weight, 1 Moore, *supra* at 1503; indeed, he states explicitly:

> "When 28 U. S. C. § 1391(c) was enacted it represented a marked change in the former statutes and some substantial change in the practice." 1 Moore, *supra* at 1493.

There are thus no obstacles to the adoption of a good sense, rational construction of Section 1391(c)—that in cases governed by the general venue provisions of Section 1391, the definition of corporate residence in Section 1391 (c) applies to corporate plaintiffs as well as corporate defendants. This result is called for both by the "liberalizing purpose underlying" the enactment of Section 1391(c)—"to bring venue law in tune with modern concepts of corporate operations"—and by the "generality of . . . language" used in Section 1391(c). *Pure Oil Co.* v. *Suarez*, 384 U. S. 202, 204-05 (1966).

B. In any event, even if the definition of corporate residence in Section 1391(c) does not apply to corporate plaintiffs in all cases in which venue is governed by Section 1391, the reasons for the enactment of Section 1391(e)(4) require that this definition apply in cases falling within that section.

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[20] The District Court apparently concluded (R. 46) that Congress, in enacting § 1391(c), intended to do no more than codify the doctrine announced by this Court in Neirbo Co. v. Bethlehem Shipbuilding Corp., 308 U. S. 165 (1939), that a corporation waives its venue privilege by becoming licensed to do business in a state. As Professor Moore points out, however, § 1391(c) is broader than the *Neirbo* doctrine. 1 Moore, *supra* at 1493.

There can be no dispute that in enacting Section 1391(e) in 1962, Congress intended to broaden significantly the venue provisions in actions instituted against Federal officials.[21] Thus, even if as the District Court determined, Congress did not in 1948 intend what that Court concluded would be a "far-reaching" change were Section 1391(c) applicable to corporate plaintiffs in, for example, the typical diversity case, this conclusion does not bear on the proper interpretation of Section 1391(e). Whatever may have been the situation in 1948, the focus must be on the action of Congress in 1962, and the issue here should be decided so as best to effectuate the purpose of Congress in enacting Section 1391(e) in 1962.

The decisions below, when viewed in this light, are erroneous and should be reversed. These decisions are not consistent with the policy of Congress to give paramount consideration to the needs of private litigants, who often carry on their businesses far from their states of incorporation, and to lessen the burden on the District Court for the District of Columbia.[22] Specifically, where there are a

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[21] "The bill . . . is intended to facilitate review by the Federal courts of administrative actions. To attain this end, the bill . . . broadens the venue provisions of title 28 of the United States Code. . . ." S. Rep. No. 1992, 87th Cong., 2d Sess. 2 (1962); see H. R. Rep. No. 536, 87th Cong., 1st Sess. 1-2 (1961).

[22] "The Government official is defended by the Department of Justice whether the action is brought in the District of Columbia or in any other district. U. S. attorneys are present in every judicial district. Requiring the Government to defend Government officials and agencies in places other than Washington would not appear to be a burdensome imposition.

"On the other hand, where a citizen lives thousands of miles from Washington, . . . to require that the action be brought in Washington is to tailor our judicial processes to the convenience of the Government rather than to provide readily available, inexpensive judicial remedies for the citizen who is aggrieved by the workings of Government.

* * *

"[T]he present venue provision results in a concentration of these actions in the District Court for the District of Colum-

number of plaintiffs, as in the instant action, the effect of the decisions below is to require plaintiffs to bring a multiplicity of suits in the Federal courts of their states of incorporation or a consolidated suit in the District of Columbia.

On the other hand, the interpretation of Section 1391 (e) urged by the petitioners is in accord with the legislative history of Section 1391(e) and carries out the purpose of Congress in enacting that section. The difficulties, noted above, which are presented by the restrictive view of Section 1391(e) adopted by the courts below are eliminated by incorporating into the word "resides" in Section 1391(e)(4) the definition of corporate residence in Section 1391(c). When this is done, it is clear that venue is proper as to each petitioner in this case which is incorporated in Delaware, licensed to do business in Delaware, or doing business in Delaware. Since the respondents showed only that a number of petitioners were not incorporated in Delaware, the courts below erred in dismissing those petitioners from this action.

CONCLUSION

The judgments of the Court of Appeals should be reversed and the case remanded to the Court of Appeals for a determination of the substantive issue in this case—the legality of the respondents' regulations as to which there

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bia, a court which is already heavily burdened. Court congestion is increased and substantial delays are incurred. The broadened venue provided in this bill will assist in achieving prompt administration of justice by making it possible to bring these actions in courts throughout the country, many of which are not nearly as burdened as the District Court for the District of Columbia." S. Rep. No. 1992, 87th Cong., 2d Sess. 3 (1962); see H. R. Rep. No. 536, 87th Cong., 1st Sess. 3 (1961).

has been a basic dispute since their promulgation in 1963. The public interest and the interests of all those affected by the issue—the Food and Drug Administration, all the petitioners and every other company in the prescription drug industry, as well as the medical profession—will be served by a resolution of the merits of this controversy. Plainly put, it is truly shameful that the resources of the petitioners and of the agencies of the United States Government, and the time of busy Federal courts, have had to be expended for several years in dealing with procedural skirmishes designed by respondents to avoid review by the courts of enforcement regulations which respondents formally promulgated and as to which there is a well-grounded, basic claim of illegality.

The issue of the validity of the regulations was squarely presented on the record for decision by the Court of Appeals. Regardless of the disposition of the venue question as to the petitioners not incorporated in Delaware, there are twelve petitioners as to whom venue is concededly proper and who are entitled to an adjudication. There is no controverted issue of fact, and the regulations would adversely affect an entire industry which has been earnestly seeking since 1963 consideration of the merits of the issue. Both the Declaratory Judgment Act and the Administrative Procedure Act called for the Court of Appeals to have decided the merits. Had the Court of Appeals given effect to these basic jurisdictional statutes and to the principles enunciated by this Court in its controlling

decisions, the merits would have been reached and decided. The Court of Appeals should be directed to do so now.

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APPENDIX

I. Statutes

Declaratory Judgment Act, 28 U. S. C. §§ 2201-02 (1964):

"§ 2201. Creation of remedy.

"In a case of actual controversy within its jurisdiction, except with respect to Federal taxes, any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such."

"§ 2202. Further relief.

"Further necessary or proper relief based on a declaratory judgment or decree may be granted, after reasonable notice and hearing, against any adverse party whose rights have been determined by such judgment."

Administrative Procedure Act, § 10, 60 Stat. 243 (1946), 5 U. S. C. § 1009 (1964):

"Sec. 10. Except so far as (1) statutes preclude judicial review or (2) agency action is by law committed to agency discretion—

"(a) Right of review.—Any person suffering legal wrong because of any agency action, or adversely affected or aggrieved by such action within the meaning of any relevant statute, shall be entitled to judicial review thereof.

"(b) Form and venue of action.—The form of proceeding for judicial review shall be any special statutory review proceeding relevant to the subject matter in any court specified by statute or, in the

absence or inadequacy thereof, any applicable form of legal action (including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus) in any court of competent jurisdiction. Agency action shall be subject to judicial review in civil or criminal proceedings for judicial enforcement except to the extent that prior, adequate, and exclusive opportunity for such review is provided by law.

"(c) Reviewable acts.—Every agency action made reviewable by statute and every final agency action for which there is no other adequate remedy in any court shall be subject to judicial review. Any preliminary, procedural, or intermediate agency action or ruling not directly reviewable shall be subject to review upon the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final shall be final for the purposes of this subsection whether or not there has been presented or determined any application for a declaratory order, for any form of reconsideration, or (unless the agency otherwise requires by rule and provides that the action meanwhile shall be inoperative) for an appeal to superior agency authority.

* * *

"(e) Scope of review.—So far as necessary to decision and where presented the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of any agency action. It shall . . . (B) hold unlawful and set aside agency action, findings, and conclusions found to be (1) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; . . . [or] (3) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right. . . ."

Judicial Code, § 1391, 28 U. S. C. § 1391 (1964):

"§ 1391. Venue generally.

* * *

"(c) A corporation may be sued in any judicial district in which it is incorporated or licensed to do business or is doing business, and such judicial district shall be regarded as the residence of such corporation for venue purposes.

* * *

"(e) A civil action in which each defendant is an officer or employee of the United States or any agency thereof acting in his official capacity or under color of legal authority, or an agency of the United States, may, except as otherwise provided by law, be brought in any judicial district in which: (1) a defendant in the action resides, or (2) the cause of action arose, or (3) any real property involved in the action is situated, or (4) the plaintiff resides if no real property is involved in the action.

"The summons and complaint in such an action shall be served as provided by the Federal Rules of Civil Procedure except that the delivery of the summons and complaint to the officer or agency as required by the rules may be made by certified mail beyond the territorial limits of the district in which the action is brought."

Federal Food, Drug, and Cosmetic Act, § 502(e)(1), 52 Stat. 1050 (1938), as amended by § 112(a) of the Drug Amendments of 1962, 76 Stat. 790, 21 U. S. C. § 352(e)(1) (1964):

"Sec. 502. A drug or device shall be deemed to be misbranded—

* * *

"(e)(1) If it is a drug, unless (A) its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or

the chemical formula), (i) the established name (as defined in subparagraph (2)) of the drug, if such there be, and (ii), in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient . . . and (B) for any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient: *Provided*, That to the extent that compliance with the requirements of clause (A) (ii) or clause (B) of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary."

Federal Food, Drug, and Cosmetic Act, § 502(n), added by § 131(a) of the Drug Amendments of 1962, 76 Stat. 791, 21 U. S. C. § 352(n) (1964):

"Sec. 502. A drug or device shall be deemed to be misbranded—

* * *

"(n) In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name as defined in section 502(e), printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under section 502(e), and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with the procedure specified in section 701(e) of this Act. . . ."

Federal Food, Drug, and Cosmetic Act, § 701, 52 Stat. 1055 (1938), as amended, 21 U. S. C. § 371 (1964):

"(a) The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is vested in the Secretary.

* * *

"(e)(1) Any action for the issuance, amendment, or repeal of any regulation under section 401, 403(j), 404(a), 406, 501(b), or 502(d) or (h) of this Act shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2) of this subsection, the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

"(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) of this subsection is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3) of this subsection, the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specify-

ing those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

"(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

"(f)(1) In a case of actual controversy as to the validity of any order under subsection (e) of this section, any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. . . .

* * *

"(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law."

II. Regulations

Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act, §§ 1.104(g), 1.105(b), 28 Fed. Reg. 6375, 6376 (1963), 21 C. F. R. §§ 1.104(g), 1.105(b) (1965):

"§ 1.104 Drugs; statement of ingredients.

* * *

"(g)(1) If the label or labeling of a prescription drug bears a proprietary name or designation for the drug or any ingredient thereof, the established name, if such there be, corresponding to such proprietary name or designation, shall accompany each appearance of such proprietary name or designation. The established name shall be placed in direct conjunction with the proprietary name or designation, and the relationship between the proprietary name or designation and the established name shall be made clear by use of a phrase such as 'brand of,' preceding the established name, or by brackets surrounding the established name.

"(2) The established name shall be printed in letters that are at least half as large as the letters comprising the proprietary name or designation with which it is joined, and the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, layout, contrast, and other printing features.

"§ 1.105 Prescription-drug advertisements.

* * *

"(b)(1) If an advertisement for a prescription drug bears a proprietary name or designation for the drug or any ingredient thereof, the established name, if such there be, corresponding to such proprietary name or designation, shall accompany each appearance of such proprietary name or designation. The established name shall be placed in direct conjunction

with the proprietary name or designation, and the relationship between the proprietary name or designation and the established name shall be made clear by use of a phrase such as 'brand of,' preceding the established name, or by brackets surrounding the established name.

"(2) The established name shall be printed in letters that are at least half as large as the letters comprising the proprietary name or designation with which it is joined, and the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, layout, contrast, and other printing features."

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In the Supreme Court of the United States

OCTOBER TERM, 1966

No. 39

ABBOTT LABORATORIES, ET AL., PETITIONERS

v.

JOHN W. GARDNER, SECRETARY OF HEALTH, EDUCATION, AND WELFARE, AND JAMES L. GODDARD, COMMISSIONER OF FOOD AND DRUGS

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE RESPONDENTS

OPINIONS BELOW

The opinion of the court of appeals (R. 66–74) is reported at 352 F. 2d 286. The opinion of the district court (R. 41–55) is reported at 228 F. Supp. 855.

JURISDICTION

The judgments of the court of appeals were entered on November 1, 1965 (R. 65, 74–75). The petition for a writ of certiorari was filed on December 15, 1965, and was granted on February 28, 1966 (R. 75; 383 U.S. 924). The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

QUESTIONS PRESENTED

1. Whether interpretive regulations issued by respondents with respect to the provisions of the 1962 Drug Amendments to the Federal Food, Drug and Cosmetic Act may be challenged by petitioners, prior to enforcement, in an action seeking declaratory and injunctive relief.

2. Whether the regulations properly construe the provisions of the 1962 amendments.

3. Whether corporations doing business in a State but not incorporated therein may bring a civil suit in that State against federal officers under 28 U.S.C. 1391(e)(4).

STATUTES AND REGULATION INVOLVED

The relevant statutes and regulation appear in the Appendix, *infra*, pp. 67–74.

STATEMENT

Section 502(e)(1)(B) of the Federal Food, Drug and Cosmetic Act, enacted as part of the Drug Amendments of 1962, 76 Stat. 780, 790, requires "the established name" of any prescription drug to be "printed prominently" on any label and on any labeling in which any proprietary name of the drug appears "in type at least half as large as that used thereon for any proprietary name or designation for such drug" (p. 68, *infra*). Since there are drugs with one established name but different trade names—*e.g.*, "meprobamate" (sold under that name as well as under the proprietary names "Miltown" and "Equanil")—Congress adopted the above provision and Section 502(n)

(1)[1] to bring to the attention of prescribing physicians the established as well as the proprietary name under which a drug is promoted and thereby to encourage physicians to prescribe the least expensive drug to their patients.[2]

On February 14, 1963, the Commissioner of Food and Drugs, invoking his authority to promulgate regulations for the "efficient enforcement" of the Act (Section 701(a), 21 U.S.C. 371(a), p. 69, *infra*) and exercising his discretion to invite public participation in their formulation (see Section 4 of the Administrative Procedure Act, as recodified, 5 U.S.C. 553), announced proposed regulations. These regulations provided that the established or generic name of a prescription drug accompany each appearance of any trade name on labels, labeling and advertising. 28 Fed. Reg. 1448. The Pharmaceutical Manufacturers Association ("PMA") and several of its member firms submitted written comments, challenging the proposed interpretation as contrary to the statutory purpose. No requests for exemption on the basis of a showing of impracticability were made (Section 502(e)(1)

[1] Section 502(n)(1) requires "the established name" to appear in all advertisements and descriptive matter issued with respect to the drug and for it "to be printed prominently and in type at least half as large as that used for any trade or brand name thereof" (p. 69, *infra*).

[2] The evidence before Congress showed that drugs purchased under their established names cost one-third or one-half less than the same drug sold under the proprietary names. See 108 Cong. Rec. 17367–17368, 17381–17383. See also the views of Senators Kefauver, Dodd, Carroll, Hart, and Long. S. Rept. No. 1744, Part I, 87th Cong., 2d Sess., pp. 33–36, 38–39, 46–51.

(B)). The regulations were adopted in final form on June 20, 1963, 28 Fed. Reg. 6375.

In September 1963, PMA and 37 of its members (R. 4–7), instituted suit in the United States District Court for the District of Delaware under the Declaratory Judgments and Administrative Procedure Acts (pp. 67–68, *infra*), seeking a declaration that the "every time" interpretation embodied in the regulations (21 C.F.R. 1.104(g)(1); 21 C.F.R. 1.105(b)(1); pp. 73–74, *infra*) constituted an unwarranted expansion of statutory authority and requesting an injunction against enforcement of the regulations (R. 4–18). The plaintiffs alleged, *inter alia,* that the "every time" requirement would adversely affect the readability of their promotional material and that compliance with the regulations would make a substantial proportion of their promotional material unusable and require major revision at substantial expense (R. 14–16). Respondents moved to dismiss on the ground, *inter alia,* that the complaint failed to allege an "actual controversy" cognizable under the Declaratory Judgments Act (R. 18–21).

On cross-motions for summary judgment (R. 18–21, 22–23), the district court ruled that venue was improper for 26 of the corporate plaintiffs which were not incorporated in Delaware (R. 43–46), but otherwise granted the relief sought by petitioners (R. 62–63). The court found that the existence of the regulations posed a threat of imminent harm to petitioners and were "ripe" for judicial review (R. 48–50). Holding on the merits that the "every time" requirement was inconsistent with the statutory command

(R. 51–55), the court declared the regulations invalid and enjoined respondents from enforcing them by any administrative action or civil or criminal proceeding (R. 62–63).

The court of appeals affirmed as to the venue ruling (352 F. 2d 524), but otherwise reversed the judgment of the district court. Without reaching the question of the validity of the regulations, the court of appeals held that judicial review was unavailable at this juncture because: (1) it found in the statutory scheme a Congressional intent to preclude judicial review of the type of regulations here involved "prior to the enforcement stage" (R. 70)[1] and (2) because the fact that there was "[n]o specific case * * * presented, no immediate prosecution threatened" (R. 72) meant that there was no "'actual case or controversy' required for justiciability" under the Declaratory Judgments and Administrative Procedure Acts (R. 73–74).

SUMMARY OF ARGUMENT

I

A. The judicial review provisions of the Food, Drug and Cosmetic Act of 1938 expressly authorize pre-enforcement review only with respect to certain enumerated kinds of regulations. The specified regulations are "legislative" in character—*i.e.*, they constitute an exercise by the Food and Drug Adminis-

[1] An "enforcement" proceeding (by way of injunction, seizure or criminal prosecution) may be instituted by the Attorney General on a charge of misbranding. Particularized review may also arise through review of administrative orders relating to new drug clearance (Section 505, 21 U.S.C. 355) and antibiotic certification (Section 507, 21 U.S.C. 357).

tration of a delegated power to fill in the details of a statutory provision. Review of "interpretive" regulations—*i.e.*, those which announce the agency's understanding of a statutory rule—are not explicitly made reviewable, and we submit that an examination of the legislative history demonstrates that Congress did not contemplate that they would be subjected to judicial scrutiny at a threshold stage.

The review provisions were the product of extensive debate and negotiation in Congress. The reports and discussions on the floor indicate that whereas the proponents of liberal review provisions wished to make every regulation issued by the agency reviewable immediately, the sponsors of the Act were concerned lest a multiplicity of suits frustrate the realization of the legislation's reforms. As a compromise, it was agreed that certain "legislative" regulations could be reviewed in expedited proceedings. Congress must have acted on the premise that such review was generally unavailable under existing law, otherwise the extensive debate over how to limit early access to the courts would have been meaningless.

B. The clause of the judicial review provisions which preserved the "other remedies provided by law" (Section 701(f)(6); p. 72, *infra*) did not make the regulations involved here reviewable prior to their enforcement. The savings clause applied, by its plain terms, to the remedies afforded *in the judicial review section;* no remedies were there afforded with respect to regulations of the kind involved here. We submit that all that Congress intended to preserve in

the savings clause was the right to judicial relief in certain limited extraordinary situations.

C. Subsequent amendments to the Food, Drug and Cosmetic Act demonstrate Congress' continued intention to limit early judicial review to certain major "legislative" regulations. These amendments are particularly significant in light of this Court's earlier conclusion in *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U.S. 594, that review of action by the Food and Drug Administration is to be narrowly confined.

D. Liberal pre-enforcement review would substantially interfere with the administration of the Food, Drug and Cosmetic Act. Many interpretive and procedural regulations have been promulgated and each affects a substantial number of potential plaintiffs. Hence the possibility of a multiplicity of suits is by no means fanciful.

II

The regulations are not, in any event, "ripe" for judicial review. They do not impose a substantial and imminent injury on petitioners, and petitioners have a perfectly adequate remedy if they wait for an enforcement action or seek certification of a new drug. Nor are the regulations "final" in the sense that they reflect the views of the enforcing authority. The Attorney General, and not the Food and Drug Administration, has the power to enforce the Act by seizure or criminal prosecutions. Finally, the factual context of a specific case will assist a reviewing court in determining the proper scope of the statute and its application to the circumstances covered by the regulations.

III

If the Court concludes that the questions presented by petitioners' challenge to the regulations may properly be reviewed at this juncture, we urge that this Court decide the merits so as not unnecessarily to extend this already protracted litigation. On the merits, we believe that the applicable statute (Section 502(e)(1)(B)) was properly construed by the Food and Drug Administration as requiring the established name of a drug to accompany each appearance of the proprietary name on labels or labeling. The legislative history discloses that, after some disagreement between the House and the Senate, a Conference Committee determined that the established name should appear "wherever" the brand name is used. That understanding was confirmed by the remarks on the floor of Congress of Senator Kefauver, a staunch supporter of the legislation.

IV

Venue was improper as to the twenty-six corporate defendants who were not incorporated in Delaware. Section 1391(c) of Title 28 applies, by its terms, only to corporate *defendants*, and no sufficient policy justification has been suggested by petitioners to warrant an expansive reading of that venue provision for purposes of 28 U.S.C. 1391(e).

ARGUMENT

The principal issue in this case is whether the validity of interpretive Food & Drug regulations may be judicially challenged prior to any attempt at en-

forcement in a particular case either through further administrative proceedings or by the institution of civil or criminal actions for non-compliance with their requirements. We concur in the conclusion of the court of appeals—although we reason somewhat differently—that the validity of the "every time" regulations is not subject to review at this pre-enforcement juncture. First, we urge that Congress in the Federal Food, Drug, and Cosmetic Act did not intend that there be judicial review of this kind of regulation ("interpretive" as distinguished from "legislative") prior to its challenge within the framework of a concrete case. As a second independent ground, we argue that, even if the Congressional purpose is not sufficiently plain to draw any dispositive conclusions as to reviewability, review should in any event be deemed presently unavailable since the "every time" regulations are not "ripe" for judicial review.

I

UNDER THE FEDERAL FOOD, DRUG AND COSMETIC ACT CONGRESS DID NOT INTEND TO AUTHORIZE JUDICIAL REVIEW OF THE VALIDITY OF INTERPRETIVE REGULATIONS (SUCH AS THE "EVERY TIME" REGULATIONS INVOLVED HERE) IN ADVANCE OF AN ENFORCEMENT PROCEEDING

There can be no doubt that "[a]ll constitutional questions aside, it is for Congress to determine how the rights which it creates shall be enforced." *Switchmen's Union* v. *National Mediation Board*, 320 U.S. 297, 301. Just as Congress has power to decree that there be no judicial review of administrative action at all (in the absence of a constitutional claim) so

it may determine at what stage of the administrative process judicial review should be available. We submit that the Congressional purpose underlying the judicial review provisions of the Federal Food, Drug and Cosmetic Act—both in its original enactment in 1938 and in later amendments—was to preclude judicial review of the validity of interpretive regulations (such as those involved here) in the abstract, leaving such questions to be determined within the limits of a particular case, sharpened and refined by a particularized factual context.

An analysis of the review provisions of the 1938 Act in light of their substantial legislative history demonstrates, we believe, that Congress was seriously concerned with the possibility that premature judicial intervention might do great harm to the sweeping reforms instituted by the legislation. This history indicates that, after much debate and compromise, Congress determined to confine narrowly the instances in which the Food and Drug Administration's regulations might be reviewed prior to their enforcement. This compromise reflected an awareness of the fact that many provisions of the Act delegated to the agency a quasi-legislative function, and that the persons or corporations subject to such interstitial legislation were entitled to a prompt authoritative determination of the question whether a particular challenged regulation exceeded the power conferred by Congress. The original purpose of the review provisions—to permit judicial supervision of "legislative" regulations—has been carried forward in Congress' later amend-

ments to the Act, which authorize pre-enforcement review only in select cases.

A. THE LEGISLATIVE HISTORY[4] OF SECTION 701(F)(1) AND RELATED PROVISIONS DEMONSTRATES THAT CONGRESS INTENDED SECTION 701(F)(1) TO BE THE EXCLUSIVE AVENUE OF PRE-ENFORCEMENT JUDICIAL REVIEW OF FOOD AND DRUG REGULATIONS IN ALL BUT EXCEPTIONAL CASES.

The only provisions for judicial review of agency regulations in the Federal Food, Drug and Cosmetic Act of 1938 were those appearing in Section 701(f) of the Act, now 21 U.S.C. 371(f) (pp. 71–72, *infra*). Subsection (a) of Section 701 generally authorized the Secretary of Agriculture to promulgate regulations "for the efficient enforcement of this Act" (p. 69, *infra*). Certain kinds of regulations were enumerated in subsection (e) and, with respect to these, the Secretary was directed to convene public hearings in which "any interested person" was entitled to participate. Such regulations were not to be put into effect until ninety days after public issuance of an order based on the hearing. Subsection (f) provided for judicial review, "[i]n a case of actual controversy as to the validity of any order under subsection (e)" if a petition was filed within that 90-day period in a court of appeals. Subsection (f) then concluded with a proviso that "[t]he remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law."

The very specific enumeration in Section 701(e), and Section 701(f)'s limitation of judicial review to

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[4] Dunn, *Federal Food, Drug and Cosmetic Act* (1938) (hereinafter referred to as "*Dunn*") contains the full legislative history of the 1938 Act.

cases "of actual controversy as to the validity of any order under subsection (e)" were not the products of inattentive or hurried draftsmanship; they emerged as a deliberate compromise from the vigorous discussions and disagreements on the floor of Congress and in committee reports over the appropriate nature and extent of pre-enforcement judicial intervention. The view of the strongest proponents of strict regulation was typified by the initial version of the Act, the so-called "Tugwell bill" which was introduced in 1933 at the first session of the Seventy-Third Congress. That bill (S. 1944) contained no provision whatever for judicial review, although it authorized the Secretary of Agriculture to prescribe a wide variety of legislative regulations (*Dunn* 37–50). A successor bill had broad judicial review provisions which empowered district courts "to restrain by injunction * * * the enforcement * * * of any regulation * * * if it is shown that the regulation is unreasonable, arbitrary or capricious, or not in accordance with law * * *." Sec. 23, S. 2000, 73d Cong., 2d Sess. (1934), Dunn 66. See also Sec. 23, S. 2800, 73d Cong., 2d Sess. (1934), *Dunn* 86.[8] Attention was called to this change on the floor of the Senate, and the Senator who had introduced the measure argued that it substantially increased the legislation's fairness and obviated much of the criticisms leveled at the predecessor bill. 78 Cong. Rec. 8958–8959 (1934), *Dunn* 157–159.

[8] These bills also subjected the kinds of regulations now enumerated in Section 701(e) to the approval of a Committee on Public Health and a Committee on Food, which were to be appointed by the President. See *Dunn* 65–66, 69, 85.

Essentially the same broad provision was included in a similar bill introduced in the 74th Congress. Sec. 702, S. 5, 74th Cong., 1st Sess., (1935), *Dunn* 200. The Senate Committee on Commerce then expanded the provision by authorizing district courts not merely to enjoin the enforcement of regulations but also "to grant appropriate injunctive relief from any act or omission of any officer, representative, or employee of the Department in the administration of this Act, if it has been shown that such act or omission is unreasonable, arbitrary, or capricious * * *." *Dunn* 225. The Committee's amendment was approved by the Senate (79 Cong. Rec. 4863 (1935), *Dunn* 330–331) as was the entire bill (79 Cong. Rec. 8356 (1935), *Dunn* 510).

The bill was then sent to the House, where it was thoroughly redrafted by the House Committee on Interstate and Foreign Commerce. The revision eliminated the judicial review provision altogether. H. Rept. No. 2755, 74th Cong., 2d Sess. (1936), pp. 8–9, *Dunn* 542–543. The committee explained that a specific review provision was unnecessary because "[t]here is always an appropriate remedy in equity * * * and furthermore the committee is of the opinion that ample protection is given by the so-called Declaratory Judgments Act * * *." H. Rept. No. 2755, 74th Cong., 2d Sess. (1936), p. 8, *Dunn* 557. After limited discussion, in the course of which the absence of a judicial review provision was attacked (80 Cong. Rec. 10243–10244, *Dunn* 593–594), the House passed its redrafted version (80 Cong. Rec.

10244, *Dunn* 596). In conference, however, the judicial review provision which had passed the Senate was restored. 80 Cong. Rec. 10517, *Dunn* 609. The bill was never enacted, however, because the House and Senate could not agree on whether to assign some duties under the Act to the Federal Trade Commission. 80 Cong. Rec. 10680 (1936), *Dunn* 633.

The bill which was ultimately enacted was introduced in the 75th Congress, 1st Session as S. 5. Subsections (a), (b), (c), and (d) of Section 24 of that bill were substantially identical with the parallel subsections of Section 701 of the Act in its final form (see pp. 69–72, *infra*).* They authorized the Secretary of Agriculture to promulgate regulations "for the efficient enforcement" of the Act. Section 24(c) enumerated certain kinds of regulations—substantially those now listed in Section 701(c)(1) (p. 69, *infra*)—and required public hearings and a 90-day waiting period before such regulations could take effect. *Dunn* 650–651. Section 30 of the bill broadly authorized judicial review, substantially as had been proposed in the legislation which passed the Senate in the prior Congress. District courts were empowered by this bill to enjoin not merely regulations promulgated under Section 24(c), but "any regulation promulgated in accordance with Section 24" (including, in other words, regulations promulgated "for * * * efficient enforcement") and to grant injunctive relief against acts or omissions of officials of the Department of

*In its present form, of course, the Act assigns to the Secretary of Health, Education, and Welfare the duties which had been conferred by the 1938 Act on the Secretary of Agriculture.

Agriculture. *Dunn* 653–654. The bill was amended by the Senate Committee in certain respects which are not relevant here and was passed in the Senate. *Dunn* 746.

The House Committee on Interstate and Foreign Commerce again redrafted the entire bill. This time it did not eliminate the judicial review provision, but substituted an additional subsection in what had been Section 24 in the Senate bill and became Section 701 of the House legislation. That subsection authorized judicial review in a district court "[i]n a case of actual controversy *as to the validity of any order under subsection (e)* * * *." *Dunn* 810–811 (emphasis added).

The accompanying House report (H. Rept. No. 2139, 75th Cong., 3d Sess. (1938), pp. 9–12; *Dunn* 823–824) stated that "Section 701(e), (f), (g) of the committee amendment set forth the procedure governing the formulation and judicial review of certain regulations to be issued by the Secretary" and then significantly pointed out (*Dunn* at 824; emphasis added):

> Such regulations are *not merely interpretive. They have the force and effect of law and must be observed.* Their violation may result in the imposition of criminal penalties, or in the confiscation of the goods involved if shipped in interstate commerce, or in their exclusion from the country if imported.

The report further noted that the special review section would "permit an early determination of the validity of the Secretary's action with respect to any proposal for a regulation, amendment, or repeal, and

make for prompt certainty as to legal rights" (*Dunn* 825). The report noted further, referring to the language which now appears in section 701(f)(6) (p. 72, *infra*), that there "is also saved as a method to review a regulation placed in effect by the Secretary whatever rights exist to initiate a historical proceeding in equity to enjoin the enforcement of the regulation, and whatever rights exist to initiate a declaratory judgment proceeding" (*ibid.*). No explanation was offered as to what those rights were and how this procedure fitted into the statutory scheme.

The proposed review provisions met with strong opposition from a minority of the House Committee, the Secretary of Agriculture, the Department of Justice and various consumer organizations. The House minority noted that the review provisions related to regulations the issuance of which went to "the very heart of any worthy food and drug legislation [and that] [i]f the public health and welfare are to be adequately safeguarded, regulations putting these provisions into effect should be promptly and effectively enforceable * * *" (H. Rept. No. 2139, 75th Cong., 3d Sess., Part 2, pp. 1–3, *Dunn* 834). The principal objection of the minority was that district court review could be used as a delaying tactic, seriously impeding the effective enforcement of the Act (*Dunn* 835). It concluded that "the extraordinary provision for court review of regulations in section 701(f), * * * would postpone indefinitely the consumer protection * * *" (*Dunn* 836). In the same vein, the Secretary of Agriculture in a letter to Congressman Mapes, a committee member, pointed out that the regulations covered

by 701(f) review related to the exercise of "quasi-legislative power" to complete and effectuate the congressional will and that if the broad reach of 701(f) providing for district court review were not limited it would so "hamstring" the Act's enforcement "as to amount to a practical nullification of the substantial provisions of the bill" (*Dunn* 836-837). Similar fears were expressed by a wide variety of consumer organizations and members of Congress. See, *e.g.*, 83 Cong. Rec. 7772–7773, 7775–7777, 7779, 7785–7786, 7787–7788, *Dunn* 839–840, 842–845, 858–863, 876–880, 883–884).

On the other hand, the industry pressed for broad pre-enforcement review to forestall any possible usurpation of administrative power by the issuance of regulations having the effect of law without a close judicial check on the exercise of that power. In debating the Committee provision in the House, Congressman Lea (Chairman of the House Committee) stressed that the regulations as to which review was authorized "have the force of law, the same as if enacted by the Congress. In making those regulations the departments act as the agents of Congress," and that "the people deserve protection against arbitrary and capricious government, against inexperience and ignorance by the departments that exercise this semilegislative authority" (83 Cong. Rec. 7775, 7889–7896, *Dunn* 851, 852). Proponents of the broad pre-enforcement review provisions included, for example, fruit and vegetable producers who were concerned lest unreviewable regulations having the force of law limit

the chemical tolerances on sprays which might result in irreparable injury to their businesses (see 83 Cong. Rec. 7781, 7783, 7896–7898, *Dunn* 842–844, 867–868, 871–872, 942, 949–950). During House debate an amendment offered to transfer the review function to the courts of appeals was defeated (83 Cong. Rec. 7892, 7898, *Dunn* 931–932, 950, 962).

The bill then went to a House-Senate Conference Committee which drafted the present Section 701. In pertinent part, the accompanying Conference Report provided (H. Conf. Rept. No. 2716, 75th Cong., 3d Sess. (1938), p. 25; *Dunn* 995–996; emphasis added):

> Judicial review of the Secretary's order putting into effect a regulation under section 701 (e) under the conference agreement is had in the circuit court of appeals * * *
>
> * * * * * * *
>
> The type of judicial review provided in the agreement is as broad as the Constitution permits in the case of review by a constitutional court. *It is to be noted that the function of the Secretary in making regulations and orders to carry them out is legislative in character.* The bill as agreed in conference retains the provisions of the House bill in section 701 (e) which lays down the rules under which the regulations may be formulated and issued. Notice, hearing, and findings are required, and the Secretary must base an order only on substantial evidence of record. Judicial review of the Secretary's action to determine if there has been compliance with such requirements, whether or not there was substantial evidence to support the

findings, and, of course, upon constitutional questions, may be had.

"The provision of the House amendment under which the remedies provided for are in addition to, and not in substitution for, other legal remedies, is retained.

Again there was no elaboration as to the scope and reach of this latter provision, which became section 701(f)(6).

Without debate the compromise was agreed to in the Senate (83 Cong. Rec. 8738, *Dunn* 996). During the House Debate, Congressman Lea—a strong proponent of broad judicial review—noted that the conference was a compromise, and expressed his satisfaction with the judicial review provisions as modified. 83 Cong. Rec. 9096, 9098–9099, *Dunn* 999–1001; see also *Dunn* 1002–1007. At the same time, Congressman Reece noted that the review provisions were "worked out so as to meet with the approval of the Department of Agriculture, which, according to [his] understanding, at no time raised an objection to the bills containing a court-review provision which would enable the orders of the Department to have their validity passed upon before they become effective" (83 Cong. Rec. 9100, *Dunn* 1010). The conference bill was then agreed to (83 Cong. Rec. 9101, 9393, 9502, 9616, *Dunn* 1010, 1014–1015).

Two propositions emerge quite distinctly, we submit, from an examination of the legislative history of this provision of the 1938 Act. *First*, Congress did not believe that judicial review of regulations is

sued by the Food and Drug Administration was generally available at the pre-enforcement stage under existing law, which included the Declaratory Judgments Act, nor did it intend to create any such pre-enforcement rights generally. For had Congress contemplated that regulations such as those involved here and in the *Toilet Goods* cases (Nos. 336 and 438, this Term) could be judicially reviewed at the juncture where review is being sought here, it would hardly have been necessary to spell out, in painstaking detail, the procedure described in subsections (1), (2) and (3) of Section 701(f). Indeed, if Congress contemplated judicial review in the circumstances of this case and of *Toilet Goods*, and if it intended to preserve that remedy in subsection (f)(6)—the view of the court of appeals in the *Toilet Goods* decision, 360 F. 2d 677, 683–684, which petitioners adopt here (Pet. Br. 31–36)—it was engaging in a meaningless exercise when it provided so precisely in subsections (1), (2) and (3) for judicial review of certain kinds of regulations enumerated in subsection (e).

The enumerated regulations have an immediate and direct impact on the persons subject to them and since they are promulgated only after a full public hearing they reflect, at least as fully as do the regulations here, the considered judgment of the Food and Drug Administration. A decision adopting the standards urged by petitioners (Pet. Br. 27–30) and holding that the "every time" regulations involved here were intended to be judicially reviewable prior to enforcement would necessarily mean that the regulations enumerated in subsection (e) are similarly judicially

reviewable, even without the special authorizing provisions of subsections (f)(1)–(f)(3). But this would render meaningless the 90-day limitation of subsection (f)(1) and the thrust of the legislative debate culminating in the adoption of the rule requiring review in the court of appeals. Both of these requirements were plainly designed to insure that the legality of any challenged regulation would be expeditiously determined. See H. Rept. No. 2139, 75th Cong., 3d Sess. (1938), pp. 10–12; *Dunn* 824–826. Any person interested in delaying a judicial test of this kind of regulation could, however, under petitioners' view, wait until long after the 90-day period, and then institute a declaratory judgment suit in a district court.

Moreover, had Congress believed that a declaratory-judgment remedy was available under existing law to a person challenging any of the regulations enumerated in subsection (e), it would have been accomplishing no more by enacting sections (f)(1)–(f)(3) than providing a choice of forum to the plaintiff in such a suit. The legislative history of the review provisions indicate that Congress' purpose in vesting jurisdiction in the court of appeals was not only to expedite the review proceeding but also to meet the objections of the minority members of the House Committee who were concerned that "a single district judge could be found who would issue an injunction" against the enforcement of a regulation and who therefore opposed any provision which would "clothe each and every district judge with authority to block the enforcement of a regulation throughout the United States." H. Rept. No. 2139, Part 2, 75th

Cong., 3d Sess. (1938), p. 2; *Dunn* 835. Obviously Congress would not have been foreclosing that possibility, which concerned representatives of the Executive branch as well as legislators,[7] by merely providing an alternative remedy which a plaintiff could pursue if he chose. Congress must have assumed, we submit, that the review procedure outlined in sections 701(f)(1)–(f)(3) would be the exclusive remedy in the great majority of instances where promulgated regulations were challenged prior to enforcement.

Second, the salient legislative material shows that dispute in Congress over the review provisions was keyed to those regulations which were "legislative in character" and had "the force and effect of law." H. Rept. No. 2716, 75th Cong., 3d Sess. (1938), p. 25, *Dunn* 995. On the one hand, the Secretary of Agriculture and consumer organizations were seriously concerned that broad pre-enforcement district court review of this type of regulation would hobble the effective administration of the Act. On the other hand, it was precisely as to this type of administrative action that the industry representatives were most desirous of obtaining pre-enforcement review and thereby eliminating what they deemed to be a real threat of unbridled administrative power. In section 710(f), Congress struck a balance between the conflicting interests. Pre-enforcement review of the most significant "legislative" regulations—those which were

[7] See letter from the Secretary of Agriculture, H. Rept. No. 2139, Part 2, 75th Cong., 3d Sess. (1938), pp. 3–4; *Dunn* 838–839, and memorandum from the Department of Justice, 83 Cong. Rec. 7892–7893; *Dunn* 933–934; see also 83 Cong. Rec. 7785, *Dunn* 875–876.

promulgated under a specific Congressional grant of authority to the Secretary to set standards having the force and effect of a statute[8] was allowed, but only in the courts of appeals and only within 90 days after their issuance.[9]

The legislative history we have summarized above establishes, we believe, that this is a case of what Professor Jaffe has characterized as "implied statutory exclusion" of judicial review; it illustrates his proposition that a "statute may provide for review of an 'order' upon a record made at a hearing, from which it may be inferred that an order not based on a hearing is nonreviewable." Jaffe, *Judicial Control of*

[8] For a discussion of the difference between "legislative" and "interpretive" regulations see *Gibson Wine Co.* v. *Snyder*, 194 F. 2d 329, 331–332 (C.A.D.C.); see also, Davis, *Administrative Rules—Interpretative, Legislative, and Retroactive*, 57 Yale L. J. 919, 928–929 (1948), particularly at 932 noting with regard to the Federal Food, Drug and Cosmetic Act that the distinctions between the two types "are very real, not merely theoretical;" 1 Davis, *Administrative Law* (1958) §§ 5.03–5.04.

See also the Report of the Attorney General's Committee on Administrative Procedure (1941) pp. 99–100 (as quoted in *American President Lines, Ltd.* v. *Federal Maritime Commission*, 316 F. 2d 419, 422, n. 5 (C.A.D.C.)): "Administrative rule making, * * * includes the formulation of *both legally binding regulations* and *interpretative regulations*. The former receive statutory force upon going into effect. The latter do not receive statutory force and their validity is subject to challenge in any court proceeding in which their application may be in question" (emphasis added).

[9] Not all legislative regulations were made judicially reviewable in this fashion. The Secretary's power to promulgate regulations providing exemptions from labeling requirements where it was impracticable to comply was not made subject to the hearing procedures prescribed by subsection (a) or to the review procedures of subsection (f).

Administrative Action (1965), pp. 357–358. We emphasize that Congress did not thereby foreclose all review of regulations or orders not specifically covered by subsection (f)(1); it merely deferred such judicial scrutiny until after the agency had undertaken to enforce its announced policy. Hence this is not a case, as was *Leedom* v. *Kyne*, 358 U.S. 184, where the refusal to permit judicial review at this juncture "would mean 'a sacrifice or obliteration of a right which Congress' has given * * *." 358 U.S. at 190. At most, it means that the right, if it exists, is vindicated later, rather than now.

What we urge here with respect to the judicial review provisions of the Food, Drug and Cosmetic Act of 1938 is what this Court held those provisions to mean in *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594. In that case this Court held that a finding by the Food and Drug Administration of probable cause to seize articles as misbranded was not reviewable prior to the libel action which followed the administrative seizures. Although the Court recognized that the seizures might themselves "cause irreparable damage to a business" (339 U.S. at 599), it found that judicial review was unavailable to prevent the seizures because (339 U.S. at 600–601, emphasis added):

> Judicial review of this preliminary phase of the administrative procedure does not fit the statutory scheme nor serve the policy of the Act. Congress made numerous administrative determinations under the Act reviewable by the courts. But it did not place the finding of probable cause under § 304(a) in that category. *This highly selective manner in which Congress has provided for judicial review reinforces the*

inference that the only review of the issue of probable cause which Congress granted was the one provided in the libel suit. Cf. *Switchmen's Union* v. *Board*, 320 U.S. 297, 305–306.[10]

The *Switchmen's Union* case, on which the Court relied in *Mytinger*, stands for the same proposition—that Congress' specific enumeration of judicial remedies in a statute may be construed, where the legislative history permits, as an implied denial of any other review.

This case is governed by the same principles as were applied in *Mytinger*. Here, as in that case, the regulation represents only the view of the administrative agency; actual enforcement is in the hands of the Attorney General. 339 U.S. at 598–599. The regulations at issue here are as much a "preliminary step" (339 U.S. at 600) as the finding of probable cause in *Mytinger*. In both cases, that step may have a direct and meaningful impact on those subject to it; in *Mytinger* eleven administrative seizures of the plaintiff's product had been made within a matter of months (339 U.S. at 596). Despite this immediate effect the Court held that the plaintiff in *Mytinger* was obliged by the statutory review scheme to wait until the libel proceeding was conducted and to interpose his legal claim at that time.

Indeed, the present case involves administrative action which is even more "preliminary" than that in *Mytinger*, for the regulations here are merely the foundation for potential findings of probable cause on which future seizures may be made. Quite plainly,

[10] In a footnote, the Court noted that an order refusing a new drug application is reviewable, and that other orders relating to the regulations enumerated in Section 701(e) are also made reviewable 339 U.S. at 600–601, n. 6.

if the Food and Drug Administration had reached the conclusions stated in these regulations as an internal policy decision and not by the issuance of interpretive rules, findings of probable cause based on those conclusions would be squarely controlled, insofar as judicial review is concerned, by the *Mytinger* decision. We submit that the Food and Drug Administration's decision to publicize its interpretation of the statute after giving interested partes an opportunty to participate in their promulgation should not make reviewable the kind of threshhold decision which Congress intended to shield against the delays of immediate litigation.

B. NO DIFFERENT LEGISLATIVE INTENTION CAN BE INFERRED FROM THE ENACTMENT OF SECTION 701(f)(6)

Petitioners contend that by enacting the savings clause which appears as subsection (f)(6), Congress manifested its intention not to make the procedure outlined in subsections (f)(1)–(f)(3) the exclusive route by which pre-enforcement review could be obtained (Pet. Br. 31–36). The same view was expressed by the court of appeals in the *Toilet Goods* case (360 F. 2d at 683–684). But this argument overlooks the fact that subsection (f)(6), by its plain terms, saves only alternative remedies to those "provided for in *this* subsection"—*i.e.*, it preserves the pre-existing rights of plaintiffs challenging the regulations enumerated in subsection (e). Only those plaintiffs are accorded remedies in "*this* subsection." Subsection (f)(6) neither expressly nor impliedly deals with review of interpretive regulations such as those involved here. Nor does it even affect legisla-

tive regulations other than those specifically enumerated in subsection (e). And, as we have shown, the disagreement in Congress over the scope of subsection (f)(1) makes sense only if Congress assumed that without express legislation very few regulations would be judicially reviewable prior to enforcement.

This limited construction of subsection (f)(6) is consistent with its particular development in the legislative history of the statute. In the earlier versions of the Food, Drug and Cosmetic Act, the only remedy explicitly preserved was the "right of any person against whom a criminal prosecution or suit for injunction shall have been brought under this act or who shall intervene as claimant in any proceeding of libel for condemnation to plead that the regulation whose violation is alleged as the ground for such prosecution, suit, or libel, is invalid * * *" (*Dunn* 184, 225, 609–610). To this purely defensive remedy Congress also added, in the final versions of the bill, "whatever rights exist to initiate a historical proceeding in equity to enjoin the enforcement of the regulation, and whatever rights exist to initiate a declaratory judgment proceeding." H. Rept. No. 2139, 75th Cong., 3d Sess. (1938), p. 11, *Dunn* 825. We believe that the failure to refer to these rights explicitly in earlier drafts indicates that Congress viewed these rights narrowly and did not contemplate that either a "historical proceeding in equity" or "a declaratory judgment proceeding" could be brought simply because the agency had, on due deliberation, promulgated a regulation which was likely to affect the plaintiff's method of doing business. It must be recalled,

in this regard, that the Act was passed at a time when this Court was firmly establishing the doctrine that federal courts should not interfere prematurely in administrative proceedings. See *e.g., Myers* v. *Bethlehem Shipbuilding Corp.*, 303 U.S. 41, 50–51, decided just six months before the passage of the Food, Drug and Cosmetic Act.

What Congress had in mind in enacting subsection (f)(6) was to preserve the right to bring suit to challenge regulations promulgated under subsection (e) in exceptional instances where review under subsection (f)(1) might be unavailable. If, for example, the Food and Drug Administration undertook to promulgate legislative regulations without affording an opportunity for public participation (which would include general notice of the proposal and an opportunity to file objections and request a public hearing) an equity proceeding or a declaratory judgment action brought after the 90-day period might be entertained on the ground that the statutory procedures had not been followed. Cf. *United States* v. *3-7/12 Dozen Packages*, 59 F. Supp. 284, 289 (W.D. La), affirmed *sub nom. Byrd* v. *United States*, 154 F. 2d 62, 64 (C.A. 5); *United States* v. *Bodine Produce Co.*, 206 F. Supp. 201, 204 (D. Ariz.). But see *United States* v. *Lord-Mott Co.*, 57 F. Supp. 128 (D. Md.).

C. IN AMENDING THE ACT, SUBSEQUENT CONGRESSES HAVE MANIFESTED A SIMILAR INTENTION TO LIMIT PRE-ENFORCEMENT JUDICIAL REVIEW

Additional compelling evidence that the 1938 Act should be read as denying pre-enforcement review for

the interpretive regulations involved here emerges from an examination of the pattern by which subsequent Congresses have amended the original statute. The amendments have consistently specified the regulations which are subject to judicial review either under Section 701(f) or under specific provisions in the amendments and have been silent as to all others. The Insulin Amendments of 1941, for example (55 Stat. 851, 21 U.S.C. 356), authorized the promulgation of regulations "necessary to carry out the purposes of this section," but specified that Section 701(e) and (f) was to apply to such regulations only "insofar as they prescribe tests or methods of assay to determine strength, quality, or purity of any drug, different from the tests or methods of assay set forth for such drug in an official compendium, * * *."

In the Pesticide Chemicals Amendments of 1954 (68 Stat. 511, 21 U.S.C. 346a), Congress also provided a detailed pre-enforcement judicial review procedure for specifically enumerated kinds of orders. The review provisions, which contemplate a 60-day limitation period and expedite ultimate determination of the claim by conferring jurisdiction on the court of appeals, cannot be squared with the proposition that Congress was saving to all parties affected by a regulation the right to sue in the district court at any time before enforcement under the Declaratory Judgment Act.

The Color Additive Amendments of 1960 (74 Stat. 397, 21 U.S.C. 376) also provided that Sections 701(e) and (f) were to apply to certain of the regulations authorized by that statute but excluded from the specific enumeration the regulations applicable to exemptions

and to fees. Here again, the fair inference is that Congress was intending to make only the former subject to pre-enforcement judicial review.

Finally, the highly selective approach was followed in the Drug Amendments of 1962, which include the provision giving rise to the present dispute. Under the 1962 statute, the Secretary is authorized to adopt varied regulations, but only some are explicitly subject to formal rule-making procedures and to pre-enforcement judicial review.[11]

The 1954, 1960 and 1962 amendments are particularly significant in this regard because they followed this Court's decision in *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U.S. 594. In the *Mytinger* decision this Court narrowly construed the review provisions of the 1938 Act and held, in effect, that where review was not specifically provided, it was barred. See pp. 24–26, *supra*. By following the same pattern in amendments to the Act, and specifically in the provisions relevant here, Congress was, we submit, ratifying this Court's understanding of the statute. This reference is buttressed by Congress' repeated refusal, through the years, to accede to industry requests for specific statutory provisions giving district courts the authority to hear pre-enforcement review action brought by affected parties.[12]

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[11] See, for example, Sections 505, 508(a); 76 Stat. 784, 789. Neither Section 502(e)(1)(B) nor 502(n)(1)—the "established name" provisions under which the "every time" regulations were promulgated—refer in the portions pertinent here, to regulations, the order of their adoption, or to judicial review.

[12] See, *e.g.*, Hearings Before a Subcommittee of the House Committee on Interstate and Foreign Commerce on H.R. 4277

D. LIBERAL PRE-ENFORCEMENT REVIEW OF INTERPRETIVE AND MINOR LEGISLATIVE REGULATIONS WOULD INTERFERE WITH THE EFFICIENT ENFORCEMENT OF THE FOOD, DRUG AND COSMETIC ACT.

The limiting construction of the review provisions which we are urging here is consistent with Congress' obvious desire to establish a regulatory system which would permit as little delay as possible in the execution of the legislative objectives. Congress fixed extremely brief limitation periods for the review of those regulations which were explicitly made reviewable by Section 701(e) and (f), and in the debates over the breadth of the judicial review clause all legislators seemed to be agreed that it was desiable not to permit "the machinery [to be] hung up over long periods of time" (83 Cong. Rec. 7894, *Dunn* 939; see also 83 Cong. Rec. 7894–7895, *Dunn* 940–941).[12]

(an early draft of the "Pesticide Chemical Amendments of 1954," 68 Stat. 511), 83d Cong., 1st Sess. (1953), p. 28, *et seq.*; see also H. Rept. No. 1385, 83d Cong., 2d Sess., pp. 10–11.

[12] It is true, as petitioners argue (Pet. Br. 35), that Congressman Mapes asserted during the House debates that "existing law" permitted any individual to sue the Food and Drug Administration in his home district on the ground that an order applicable to him was "arbitrary, capricious, unreasonable, or contrary to law." 83 Cong. Rec. 7893, *Dunn* 936. But his views were almost immediately challenged. Congressman Leavy specifically responded, "I take issue with the gentlemen who say you can go into any Federal court and there get an injunction against an agent of the United States Government, for official actions." 83 Cong. Rec. 7895, *Dunn* 941. Citing the doctrine of sovereign immunity, Representative Leavy "challenged" Representative Mapes "to cite authority authorizing such general actions, as he refers to in his remarks, where the citizen can institute suit against the United States." *Ibid.* And it is not entirely irrelevant, in this regard, that the amendment in support of which Representative Mapes made the quoted assertion was defeated at the conclusion of the debate by a substantial margin. (See p. 18, *supra*).

It requires little elaboration to demonstrate that a rule of review such as petitioners are urging in this case would substantially affect the administration of the Food and Drug Act. In administering the provisions of the statute, the agency is called upon to make many interpretive rulings and to issue various regulations under Section 701(a) for the "efficient enforcement" of the Act. Part 3 of title 21 of the Code of Federal Regulations, for example, contained, as of January 1966, seventy different "Statements of General Policy or Interpretation" (21 C.F.R. 3.1–3.700), relating to widely varying subjects—*e.g.*, the use in drug manufacture of ox bile from condemned livers of slaughtered animals (21 C.F.R. 3.16) and the quantity of egg which must be present in a shampoo preparation for it to qualify as "egg shampoo" (21 C.F.R. 3.651). These regulations were issued voluntarily as guides to industry; the Food and Drug Administration was under no legal obligation to promulgate them as it did. Their publication is, however, obviously beneficial. It gives the industry an opportunity voluntarily to conform its practices to the views of the agency or to point out informally how and why the agency's position is unsound or imposes an excessive practical burden.

Many other regulations promulgated under Section 701(a) are scattered throughout title 21 of the Code of Federal Regulations, and it would cast a very heavy burden on the agency if it were obliged to litigate the validity of every clause of every regulation immediately upon publication. The burden would, of course, fall with equal weight on the courts which

would have the responsibility of adjudicating all these disputes.

Multiplicity of suits is not a remote possibility. In the present case, as in the *Toilet Goods* cases, suit was brought by a industry-wide association on behalf of all its members. But nothing in the Declaratory Judgments Act or in the rule proposed by petitioners limits this remedy to an industry-wide suit. If pre-enforcement review were held to be available for the reasons urged by petitioners, each of the plaintiffs in this action and in *Toilet Goods* would be able to sue separately in the district where that plaintiff resided. (see 28 U.S.C. 1391(e), pp. 72–73, *infra*). A judgment in favor of the Food and Drug Administration in any one of such actions would not, of course, be binding in a suit brought by another plaintiff in a different district. The debates in both legislative chambers before the passage of the 1938 Act demonstrate, we believe, a consensus within Congress that such multiplicity of suits and the resulting uncertainty would seriously impair the effectiveness of the statute. It is for this reason that, even with respect to important legislative regulations, Congress provided a 90-day limitations period for review and conferred jurisdiction on the courts of appeals.

To be sure, pre-enforcement review of legislative regulations has a disruptive effect on the administration of the Act and imposes a heavy burden on the agency and the courts. There is, however, a stronger justification for pre-enforcement review of legislative regulations. When Congress has delegated to an agency the power to promulgate specific rules to ex-

ecute a general legislative policy, the very issuance of the rules imposes legal duties on the individuals or corporations who produce or market the product which is affected. So long as the rules are fairly within the limits of the power which Congress has conferred, they will be sustained and they must, therefore, be obeyed. See, *e.g.*, *Federal Security Administrator* v. *Quaker Oats Co.*, 318 U.S. 218. But interpretive regulations merely announce the agency's understanding of a statutory obligation; the duty is imposed by the statute itself, and the agency's construction adds to it only such weight as a reasoned and presumably expert opinion may carry.

The legislative history shows, we believe, that Congress weighed the disruptive effect which pre-enforcement review would have on the administration of the Act against the interests of the industry's members in obtaining a judicial determination of the agency's power before having to comply at their peril. Where it had broadly delegated power to the agency, Congress decided that it was best, notwithstanding the delay that might be caused, to allow pre-enforcement review of regulations which were "legislative in character." H. Rept. No. 2716, 75th Cong., 3d Sess. (1938), p. 25, *Dunn* 995. This was a safeguard against abuse of the sweeping power given to the Food and Drug Administration, but it carried with it an implied rejection of the right collaterally to attack such regulations after the time to review them had expired. *United States* v. *8-7/12 Dozen Packages*, 59 F. Supp. 284 (W.D. La.), affirmed *sub nom. Byrd* v. *United States*, 154 F. 2d 62 (C.A. 5); *United*

States v. *Bodine Produce Co.*, 206 F. Supp. 201 (D. Ariz.). But see *United States* v. *Lord-Mott Co.*, 57 F. Supp. 128 (D. Md.).

As for interpretive or minor legislative regulations, neither Congress nor industry was concerned over the possibilities of abuse. Obviously the agency could not, by an interpretive regulation, convert a lawful product into an unlawful one. Nor could it, by exercising most of the limited quasi-legislative power delegated to it to issue regulations governing exceptions, substantially affect production or marketing within any of the regulated industries. With respect to such regulations it was Congress' intent, we submit, to deny all relief prior to enforcement. To construe the Act otherwise is to confer a broader power of early review, with more serious disruptive effects, when the consequence of the agency action is slight than when its pronouncement has the force of a statute.

II

THE REGULATIONS AT ISSUE HERE ARE NOT RIPE FOR JUDICIAL REVIEW

We argue alternatively that, irrespective of the precise terms or legislative history of the Federal Food, Drug and Cosmetic Act's judicial review provisions, the juncture at which review of the regulations is being sought here is an inappropriate one under the principles governing "ripeness" which have been judicially developed in decisions of this Court. By "ripeness" we mean the doctrine by which courts determine whether review of administrative action is

justified *"now* rather than *later."* Jaffe, *Judicial Control of Administrative Action* (1965) (hereinafter *"Jaffe"*), pp. 411–412, n. 63 (emphasis in the original). We believe that an evaluation of the cluster of judicially recognized considerations which enter into a determination of whether a controversy is "ripe" for judicial decision warrants the conclusion that the present dispute is premature so long as it is divorced from the specific factual context that could be presented in an enforcement proceeding.[14]

We begin with the proposition that it is ordinarily desirable to limit judicial review of administrative rule-making to factually sharpened instances where legal rights are directly at issue. Administrative agencies have been created by Congress to deal, in a specialized way, with a broad complex of subjects ranging, for example, from security regulation to patrolling labor-management disputes. Their major tool is an expertise refined by a continuing dialogue with a particular segment of the economy. Courts should not prematurely intrude on this dialogue, but should limit their intervention to the instances in which negotiation has failed.[15]

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[14] An enforcement case would arise if the penalty provisions of the Act were invoked (*i.e.*, injunction, condemnation or criminal prosecution, Sections 301–307, 21 U.S.C. 331–337). Alternatively, judicial review of the regulation would follow administrative procedures relating to new drug clearance (Section 505, 21 U.S.C. 355) or antibiotic certification (Section 507, 21 U.S.C. 357).

[15] "Negotiation is *the* major mode of administration, of resolving the continuous uncertainties of fact and law. If it is made too easy to bring every administrative expression, how-

The doctrine of "ripeness" enables the judiciary to stay its hand until the time for its entry is appropriate. In determining whether a plaintiff's challenge to an agency's action is "ripe" or "premature," emphasis has usually been placed on the three considerations we discuss below. No precise formula for determining whether a particular controversy is ripe is available, of course. As Professor Jaffe has observed, "[R]ipeness should not be determined by formula but by a reasoned balancing of certain typical and relevant factors for and against the assumption of jurisdiction." *Jaffe*, 396.

Before turning to a discussion of these elements, we emphasize that our compartmentalization is employed solely for the sake of clarity. The elements overlap and complement each other; it is in their varied combinations and permutations—not by any formalized listing—that one finds answers to questions of early reviewability. As Mr. Justice Frankfurter put the matter in *Poe* v. *Ullman*, 367 U.S. 497, 508–509:

> Justiciability is of course not a legal concept with a fixed content or susceptible of scientific verification. Its utilization is the resultant of many subtle pressures, including the appropriateness of the issues for discussion by this Court and the actual hardship to the litigants of denying them the relief sought.

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ever informal, into court, negotiations may be hampered." *Jaffe*, 410–411 (emphasis in the original); see also *Helco Products Co.* v. *McNutt*, 137 F. 2d 681 (C.A.D.C.).

See similarly his concurring opinion in *Joint Anti-Fascist Refugee Committee* v. *McGrath*, 341 U.S. 123, 149, 155–157."

A. THE REGULATIONS DO NOT PRESENT AN IMMINENT AND SUBSTANTIAL DANGER TO ANY LEGALLY COGNIZABLE INTEREST OF PETITIONERS

1. The nature and extent of the impact which challenged regulations have on those subject to the contested administrative action is plainly an essential consideration in determining ripeness. Particularly when, as here, there is ample opportunity to challenge the regulation at a later point in time, *i.e.*, after a more individualized determination by the agency, at-large regulations should not be reviewable unless they "disrupt * * * and seriously disorganize * * * business," *Columbia Broadcasting System, Inc.* v. *United States*, 316 U.S. 407, 414, or constitute an attempt to "control the business affairs" of the party seeking relief to the

[16] We also observe, at the outset, that the Declaratory Judgments Act does not compel a court to assume jurisdiction where a case is not otherwise ripe for review. It is settled that the Act "is not an independent source of federal jurisdiction." *Schilling* v. *Rogers*, 363 U.S. 666, 677; *Great Lakes Co.* v. *Huffman*, 319 U.S. 293, 300; *Alabama State Federation of Labor* v. *McAdory*, 325 U.S. 450, 461. By the same token, Section 10 of the Administrative Procedure Act, recodified as 5 U.S.C. 704, authorizing review of "final agency action," does not of itself compel review if the agency action is not "ripe." Compare the decisions so holding in "standing" cases. *Kansas City Power & Light Company* v. *McKay*, 225 F. 2d 924 (C.A.D.C.), certiorari denied, 373 U.S. 914; *Ove Gustavsson Contracting Company* v. *Floete*, 278 F. 2d 912, 914 (C.A. 2), certiorari denied, 364 U.S. 894. We do not read *Cappadora* v. *Celebrezze*, 356 F. 2d 1 (C.A. 2), as embracing contrary principles. In that case, although the Social Security Act did not provide for review on a decision not to reopen, the decision had become a "final and binding" determination so that it was reviewable under the Administrative Procedure Act.

extent that it "cannot cogently plan its present or future operations," *United States* v. *Storer Broadcasting Co.*, 351 U.S. 192, 199–200. See *Frozen Food Express* v. *United States*, 351 U.S. 40, 44. Highly illuminating in this regard is the decision in *Shields* v. *Utah Idaho Central R. Co.*, 305 U.S. 177, which concerned administrative action affecting the complainant railroad's status under many other regulatory statutes. The Court held that the plaintiff was entitled to relief because the interconnected provisions of the various federal statutes made the administrative determination a very significant one to the railroad. 305 U.S. at 182–184. See also *A.F. of L.* v. *Watson*, 327 U.S. 582, 593–596; cf. *Frozen Food Express* v. *United States*, 351 U.S. 40; *McCulloch* v. *Sociedad Nacional*, 372 U.S. 10, 16–17.

A corollary to this proposition is that judicial intervention is not warranted where the injury to the challenging party is not significant. Courts should be hesitant to step in at an early stage where the challenged regulation affects an enterprise only in a peripheral or indirect way, reaches only a narrow phase of a party's business, creates only a minor inconvenience, or requires an adjustment which does not have an impact on the fundamental structure of a business operation.[17]

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[17] Broad-reaching administrative action may be deemed ripe for immediate review where it is patently invalid on its face. See, *e.g.*, *Public Utilities Commission* v. *United Fuel Gas Co.*, 317 U.S. [illegible], 469; *Leedom* v. *Kyne*, 358 U.S. 184; *Farmer* v. *United Electrical Radio & Machine Workers*, 211 F. 2d 36, 39 (C.A.D.C.), certiorari denied, 347 U.S. 943. Review in such circumstances would be justified on principles analogous to those

Another factor which may properly be considered is the availability and efficacy of other remedies. There may be instances in which the consequences of failure to comply with the administrative directive are so severe and immediate that no realistic remedy can be said to exist at the termination of the administrative process. Thus, no test of validity may ever arise in a specific case because the party affected by the administrative action may deem compliance the only way "to avoid the unpleasant legal consequences which failure to conform entails." *Columbia Broadcasting System, Inc.* v. *United States, supra,* 316 U.S. at 417; *Bantam Books, Inc.* v. *Sullivan, supra,* 372 U.S. at 64–65, n. 6.

2. Under these standards, petitioners have not shown any compelling need for immediate review. They allege that the regulation would require them to discard their present promotional materials and to change existing labels (R. 14–16; Pet. Br. 13).[18] But mere financial expense has generally not been held a justification for early judicial intervention. *Perkins* v. *Lukens Steel Co.,* 310 U.S. 113, 125; *Allen* v. *Grand Central Aircraft Co.,* 347 U.S. 535, 539–540, and cases

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which authorize judicial intervention to strike down patently unconstitutional statutes where the very imminence of enforcement stifles the exercise of basic rights. *E.g., Dombrowski* v. *Pfister,* 380 U.S. 479; *Truax* v. *Raich,* 239 U.S. 33, 38–39; *Pierce* v. *Society of Sisters,* 268 U.S. 510, 534–536; cf. *Bantam Books, Inc.* v. *Sullivan,* 372 U.S. 58.

[18] The additional allegation that the regulations would render labels "confusing and repetitious" or misleading (R. 15) does not, of course, bear on whether review should be had now or later. If confusion is caused by the regulations, it is the public, not petitioners, who suffer the irreparable injury.

there cited. And it seems quite plain that petitioners have an adequate remedy if they continue to use their present promotional material—in accordance with their understanding of the statute—and await enforcement actions. Indeed, since the drug-clearance provisions of Section 505 (21 U.S.C. 355) and the antibiotic certification procedures of Section 507 (21 U.S.C. 357) permit pre-marketing determinations, petitioners appear to have a satisfactory remedy which would not require them to wait for an administrative seizure.

The suggestion that the drug industry may be deterred by the risk of criminal prosecution from ever testing the validity of these regulations if review is denied at this juncture is totally unreal. It is not the policy of the Food and Drug Administration to proceed in the first instance by way of criminal sanctions when, as the district court's decision discloses to be true here, its reading of the statute is subject to differences of opinion. Indeed, if this Court sustains our position on the procedural issue, it is the intention of the Food and Drug Administrator to test the validity of the regulations under the new drug-clearance provisions of Section 505 of the Act, 21 U.S.C. 355 (which provides for direct appeal to the court of appeals (Section 505(h)) or under the antibiotic certification provision of Section 507, 21 U.S.C. 357 (which also provides for direct review in the court of appeals after the administrative process has concluded and before the administrator's orders have become effective (Section 507(f)).[19]

[19] If, for unanticipated reasons, court enforcement becomes necessary, the Department of Justice will proceed only civilly.

We note further in this connection that the regulations are not, on their face, blatantly improper. See note 17, *supra*. Indeed, as we argue below (pp. 55–62, *infra*), they reflect a proper understanding of the legislative purpose and are supported by the legislative history of the Drug Amendments.

B. THE REGULATIONS DO NOT REFLECT THE FINAL JUDGMENT OF THE ENFORCING AUTHORITY

1. Only "final" agency action, as contrasted with preliminary or tentative expression of agency views, is entitled to judicial review. By "final" we mean that kind of action which justifies the conclusion that at no future time will the plaintiff suffer an impact "more conclusive, definite or substantial." *Joint Anti-Fascist Refugee Committee* v. *McGrath*, 341 U.S. 123, 149, 154, n. 4 (concurring opinion). The reason for this limitation is that the agency charged with administration of a regulatory statute must be accorded the opportunity to adjust its tentative views in light of the broad challenges which are asserted. Essentially, the same rationale underlies the "exhaustion of administrative remedies" doctrine (*e.g.*, *Myers* v. *Bethlehem Shipbuilding Corp.*, 303 U.S. 41, 50–52) which requires a party contesting an administrative decision to pursue existing administrative remedies to determine whether he will ever feel the "pinch of

for an injunction (Section 302, 21 U.S.C. 332) or by condemnation (Section 304, 21 U.S.C. 334). Multiple administrative seizures would ordinarily be unavailable since it is doubtful that there is probable cause to believe that the misbranded article is dangerous to health or that the labeling is fraudulent, misleading or injurious. See Section 304(a).

administrative action." *Federal Power Commission* v. *Hope Gas Co.*, 320 U.S. 591, 619; *Whitehouse* v. *Illinois Central R.R. Co.*, 349 U.S. 366, 373. See also *Rabinowitz* v. *Kennedy*, 376 U.S. 605, 610–611, where this Court held unripe one aspect of a declaratory judgment action challenging the administrative interpretation of the Foreign Agents Registration Act of 1938 because the claimants had failed to make any effort to determine how much information they would be required to disclose.[20]

The requirement of "finality" likewise affords the agency the freedom to develop a solution to public problems without fear that its every action will be subject to minute judicial scrutiny. Uniform, forceful and creative administration would be frustrated by easy access to the courts every time a person is affected by half-formed administrative action. For example, in *Eccles* v. *Peoples Bank*, 333 U.S. 426, the plaintiff's membership as a bank in the Federal Reserve System was conditioned by the Board of Governors on its independence from the control of holding companies. When a holding company obtained an interest in violation of this condition, the Board refused to relieve the bank of the condition but disavowed any intent to invoke it unless the public interest required such action. On that record this Court denied petitioner's request that it declare the condi-

[20] See also, *Danville Tobacco Association* v. *Freeman*, 351 F. 2d 832, 833 (C.A.D.C.), where, among the court's reasons for finding lack of ripeness as to certain appellants, was their failure to make application to see if they met the requirements of certain tobacco regulations which they were challenging judicially.

tion invalid. In reaching this conclusion, the Court pointed out that no administrative action had come to "fruition" and that "when a body such as the Federal Reserve Board has not only not asserted a challenged power but has expressly disclaimed its intention to go beyond the legitimate 'public interest' confided to it, a court should stay its hand," 333 U.S. at 434–435. See also *Continental Bank & Trust Company* v. *Martin*, 303 F. 2d 214, 218 (C.A.D.C.).

In short, the more tentative and preliminary the agency action, the less reason there is for judicial interference. In *United States* v. *Los Angeles R.R. Co.*, 273 U.S. 299, the "final valuation" sought to be reviewed was "only a preliminary, interim step toward possible future action." *Federal Power Commission* v. *Hope Gas Co.*, 320 U.S. 591, 619. Similarly, this Court's *per curiam* decision in *Public Utilities Commission* v. *United Air Lines*, 346 U.S. 402, appears to have rested on the ground that the administrative order being challenged—which directed the airline to file tariffs with the State commission—may not have reflected the final and considered views of the agency regarding its jurisdiction. This is also the essence of the much-cited case of *Helco Products Co.* v. *McNutt*, 137 F. 2d 681 (C.A. D.C.), where declaratory relief was sought challenging (1) a "letter" of the legal staff of the Food and Drug Administration concerning the statutory validity of a certain proposed shipment in interstate commerce, (2) a follow-up letter from the Food and Drug Administrator agreeing that the shipment would violate the Act, and (3) the refusal of the Attorney

General to advise petitioner if prosecution or other sanction would follow if such shipment was made. In refusing judicial review in such circumstances, the court pointed out (137 F. 2d at 684):

> To permit suits for declaratory judgments upon mere informal, advisory, administrative opinions might well discourage the practice of giving such opinions, with a net loss of far greater proportions to the average citizen than any possible gain which could accrue.[21]

Compare *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U.S. 594, 599–600.[22]

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[21] Similar holdings of non-finality were made in *Richfield Oil Corp.* v. *United States*, 207 F. 2d 864, 870 (C.A. 9); *American President Lines, Ltd.* v. *Federal Maritime Commission*, 316 F. 2d 419 (C.A.D.C.); *First Savings and Loan Association of the Bahamas, Ltd.* v. *Securities and Exchange Commission*, 358 F. 2d 358 (C.A. 5).

[22] There are, it is true, instances in which non-final agency action might be deemed "ripe" simply because the question is of great importance beyond the dispute of the parties before the court. Where an agency proposes far-reaching implementation of a statute through the adoption of regulations, public as well as private interests may best be served by having disputed issues as to the validity of the agency's actions settled at the threshold. Early legitimization of far-reaching agency action may avoid time-delaying multiplicity of litigation and give the agency an authoritative basis for proceeding in a manner that will best serve a significant public interest. Thus, in *McCulloch* v. *Sociedad Nacional*, 372 U.S. 10, the courts intervened in the early stages of National Labor Relations Board proceedings to hold that the Board had misinterpreted the National Labor Relations Act to cover maritime operations of foreign flag ships employing alien seamen. This Court recognized that the usual rule has been to avoid premature review in the labor-management field, but held that that case warranted a different approach because of the "overriding consideration * * * that the Board's assertion of power to determine the representation of foreign seamen aboard vessels under

2. We agree, of course, that the regulations involved in the present case are the product of mature administrative judgment, and are not merely preliminary or tentative agency conclusions. This does not, however, *ipso facto* render them "final" within the meaning of the criteria we have outlined above. An important element in the finality of such a regulation is the question whether the agency whose voice is heard in the regulation is the same agency to whose hands the enforcement of the statute has been entrusted. In *Frozen Food Express* v. *United States*, 351 U.S. 40, this Court held reviewable an interpretive regulation of the Interstate Commerce Commission construing the "agricultural exemption" of the Motor Carrier Act of 1935. In discussing wherein the regulation was appropriate for judicial review the Court said (351 U.S. at 44):

> Where unauthorized operations occur, the Commission may proceed administratively and issue

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foreign flags has aroused vigorous protests from foreign governments and created international problems for our Government" (372 U.S. at 16–17). The Court further said (372 U.S. at 17):

> Important interests of the immediate parties are of course at stake. But the presence of public questions particularly high in the scale of our national interest because of their international complexion is a uniquely compelling justification for prompt judicial resolution of the controversy over the Board's power.

See also *Trans World Airlines, Inc.* v. *C.A.B.*, 339 F. 2d 56, 63 (C.A. 2), certiorari denied, 382 U.S. 842; *Northeast Airlines, Inc.* v. *C.A.B.*, 345 F. 2d 662, 664–665 (C.A. 1); cf. *Brigham* v. *F.C.C.*, 276 F. 2d 628 (C.A. 5).

a cease and desist order. § 204(c). Such orders of the Commission are enforceable by the courts. § 222(b). And wilful violation of a cease and desist order is ground for revocation of a certificate or permit. § 212. The determination made by the Commission is not therefore abstract, theoretical, or academic.

Under the Federal Food, Drug & Cosmetic Act, however, the enforcement authority is lodged with the Attorney General and not with the Food and Drug Administration. And this particular separation of interpretation and enforcement powers has been deemed by this Court an indication that a challenge to administrative action alone might be premature: "Whether a suit will be instituted depends on the Attorney General, not on the administrative agency. He may or may not accept the agency's recommendation. If he does, seizures are made and libels are instituted. But the seizures and suits are dependent on the discretion of the Attorney General." *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U.S. 594, 599; see also *Helco Products Co.* v. *McNutt*, 137 F. 2d 681, 683 (C.A.D.C.).[22]

We also note that petitioners have never requested the Secretary of Health, Education and Welfare to establish "exemptions" from the "every time" reg-

[22] We do not in any way mean to suggest that the Attorney General does not act on the recommendations of the Food and Drug Commissioner or that there is any difference in view on how to proceed in this case. We mean only to note that even in its most final aspect—when it is fully matured agency action—there is still a preliminary cast to the instant regulations which differentiates them from the regulation in *Frozen Food*.

ulations on grounds of impracticability, as he is authorized to do under Section 502(e)(1)(B) of the Act. See *Rabinowitz* v. *Kennedy*, 376 U.S. 605, 610–611.[24]

C. THE FACTUAL CONTEXT OF A SPECIFIC CASE CAN CONTRIBUTE TO AN UNDERSTANDING OF THE ISSUES PRESENTED BY A CHALLENGE TO THE VALIDITY OF THE REGULATIONS

1. A significant "ripeness" factor in the field of public law is that the issue put to the court for decision should be definite and clear-cut. It is not the business of courts to decide unreal or cloudy controversies. See, *e.g.*, *United Public Workers* v. *Mitchell*, 330 U.S. 75; *Rescue Army* v. *Municipal Court*, 331 U.S. 549; *Public Service Commission* v. *Wycoff*, 344 U.S. 237; *Alabama State Federation of Labor* v. *McAdory*, 325 U.S. 450; *International Longshoremen's Union* v. *Boyd*, 347 U.S. 222; *Poe* v. *Ullman*, 367 U.S. 497; *Rabinowitz* v. *Kennedy*, 376 U.S. 605. While this doctrine has had its primary application in constitutional adjudication, it has also been recognized that "[c]ourts should avoid passing on questions of public law even short of constitutionality that are not immediately pressing." *Eccles* v. *Peoples Bank*, 333 U.S. 426, 432. Adjudication, in short, must rest on "an adequate and full-bodied record" particularly in the resolution of "delicate problems" which are "bound to have far-reaching import." *Public Affairs Press* v. *Rickover*, 369 U.S. 111, 113.

[24] This is relevant only with respect to the regulation (21 C.F.R. 1.04(g)(1)) relating to the labeling requirements of Section 502(e)(1). Section 502(n) has no exemption provision with respect to advertising material, probably because impracticability was not anticipated as a basis for noncompliance with that provision.

Factual considerations are important in another sense. Interpretive regulations, before their enforcement in a particular case, are general in their application. They cut across a wide range of varied factual situations. The question of their validity cannot, therefore, usually be determined independently of factual variables. A court must "see what legal issues it is deciding, what effect its decision will have on the adversaries, and some useful purpose to be achieved in deciding them." *Public Service Commission* v. *Wycoff*, 344 U.S. 237, 244; *United Public Workers* v. *Mitchell*, 330 U.S. 75, 90. Just as an agency could not go into court to obtain the court's seal of approval on its at-large interpretation of a statute, so is it usually impossible to determine in advance, at the behest of a private party, whether the agency's interpretation is wrong. Only if all conceivable facts to which a regulation might apply are known can a court decide with certainty whether the regulation properly interprets the statute. See, *e.g.*, *Aetna Life Insurance Co.* v. *Haworth*, 300 U.S. 227, 242, where the Court granted declaratory relief in "an adjudication of present right upon *established* facts" (emphasis added); *Pierce* v. *Society of Sisters*, 268 U.S. 510, 530, where the Court took the unusual course of striking down a statute before its enforcement where there were no "controverted questions of fact." A court may otherwise be confident of a regulation's application to most foreseeable cases, but it cannot predict with certainty whether the regulation can properly govern *all* conceivable possibilities which come within its terms.

Asking a court to make such a determination is, in effect, requesting an advisory opinion.

2. The present case illustrates, quite graphically, the inappropriateness of permitting an abstract determination of the kind sought here. The applicable statute declares drugs misbranded if their labeling does not comply with the statute. Under ordinary circumstances, the statute would be construed by a court, with the assistance of the interpretation provided by the Food and Drug Administration, in a proceeding involving the particular label or promotional labeling of a drug manufacturer or marketer. The question would then be whether the labeling meets the standards of the statute.

In the present proceeding, however, the roles of the parties have been reversed. The question is whether the governmental agency's "every time" regulation is a proper construction of the statute. In arguing that it is not, petitioners have taken three different positions: In the district court they contended that the Food and Drug Administration had the authority to regulate on the question of how prominently the generic name must appear, but that the "every time" regulation went too far (R. 30-31). In the court of appeals, petitioners argued that the statute was satisfied if the established or generic name appeared *once*, in a prominent location, on the labelling and promotional material (Ct. of App. Br. 33, 40, 42). And in the petition for a writ of certiorari it was urged that the statute would be satisfied if the established name appeared prominently "on every page in the required type size" (Pet. 11).

By resolving the issue as it did, the district court adopted none of these three positions. Consequently, petitioners, even if they prevail, are given no guidance as to the standard which the statute establishes. If the agency then issues another interpretive regulation, that too might be successfully challenged without resulting in any standard for the industry to follow.

Indeed, a more serious problem would be presented if a district court were to determine that an agency's interpretation of a statute might be warranted under some circumstances but not under others. Should it then grant relief of the kind sought here by petitioners on the ground that the regulation is not universally applicable or should it deny relief because the regulation is valid as applied to many of the foreseeable situations to which it might relate? We submit that the course chosen by this Court in *Zemel* v. *Rusk*, 381 U.S. 1, 19–20, is the appropriate one—to leave to "a concrete fact situation" the adjudication of the meaning of a statute which might conceivably be applied differently to varying circumstances.

D. PRIOR DECISIONS OF THIS COURT DO NOT CONTROL THE RIPENESS ISSUE IN THIS CASE

Petitioners contend that the "ripeness" or "justiciability" issue in this case is controlled by *Columbia Broadcasting System, Inc.* v. *United States*, 316 U.S. 407; *United States* v. *Storer Broadcasting Co.*, 351 U.S. 192; and *Frozen Food Express* v. *United States*, 351 U.S. 40 (Pet. Br. 17–20). We believe that the three cited decisions are all distinguishable from the present case.

1. In *Columbia Broadcasting System Inc.* v. *United States*, 316 U.S. 407, the Federal Communications Commission, in an attempt to curtail the monopolistic power of networks, issued the "Chain-Broadcasting" regulations controlling contracts between licensees and the networks. Despite the fact that the Commission termed the regulations an expression of "general policy" to be followed in "exercising our licensing power" (316 U.S. at 411, 422), and had issued a "supplementary minute" providing administrative and judicial proceedings whereby individual licensees could challenge the validity of the regulations (316 U.S. at 413–414), this Court permitted early review. It found that, in fact, the regulations were final administrative action (316 U.S. at 422); that if implemented "in accordance with their terms [they] would disrupt appellant's broadcasting system and seriously disorganize its business" (316 U.S. at 414); and that their validity could be fairly assessed only in a direct proceeding in which the network was the true party in interest and was not merely intervening in a licensing proceeding in which the issue might never arise (316 U.S. at 422–423). It was, in short, in very special circumstances where questions of "standing" merged with those of "ripeness"[25] and sweeping agency action was at issue, that the Court permitted judicial intervention.

[25] Professor Jaffe has noted that the question of standing *vel non* was "more acute" than that of ripeness since "[t]o deny relief here may be equivalent to a denial of all relief, in sum to a decision that the network has no 'legally protected interest.'" *Jaffe*, 402.

2. The decision in *United States* v. *Storer Broadcasting Co.*, 351 U.S. 192, was an application of the *Columbia Broadcasting System* rationale. In *Storer*, after extensive hearings, the Federal Communications Commission adopted regulations limiting the number of television stations individuals could own and providing that certain stock interests would amount to ownership. Again rejecting the argument that reviewability was unavailable to a claimant (who, if the regulations were enforced, would lose his license) because the regulations themselves did not, in a formal sense, carry a sanction for non-compliance, the Court pointed out that "final agency action was involved" (351 U.S. at 198) and that unless the licensee had an opportunity to review the validity of the agency action it "cannot cogently plan its present or future operations" (351 U.S. at 200). In *Storer*, as in *Columbia Broadcasting System*, the plaintiff was put to Hobson's choice: it could refuse to comply with the agency's regulation and thereby disqualify itself, if the regulation were sustained, from future benefits, or it might comply and thereby forfeit all opportunity ever to attack the regulation. Petitioners in the present case, as we have shown (pp. 40–42, *supra*), are put to no such difficult dilemma.

3. *Frozen Food Express* v. *United States*, 351 U.S. 40, involved an interpretive regulation concerning the scope of the "agricultural commodities" exemption in the Motor Carrier Act (351 U.S. at 41–42). The Interstate Commerce Commission itself urged early review of its regulation, pointing out that "[t]he interpretation of this agricultural commodity exemption is

of daily importance in the administration of the Act—both to the Commission and to the transportation industry." The Commission asserted that it was "high time, 20 years after enactment of the Motor Carrier Act of 1935, that the scope of the agricultural commodity exemption was settled," so as to avoid "a considerable number of court proceedings as to the status of individual commodities" (Brief for the Interstate Commerce Commission, Nos. 158–164, O.T. 1955, pp. 18, 34). Confronted with this unusual invitation from the agency charged with the enforcement of the Act requesting the resolution of a perplexing controversy, the Court found the administrative action reviewable because it went to the "basis for carriers in ordering and arranging their affairs" and because it "touches vital interests of carriers and shippers alike and sets the standard for shaping the manner in which an important segment of the trucking business will be done," 351 U.S. at 44. *Frozen Food* did involve "interpretive" rather than "legislative" regulations, and thus may properly be said to stand for the proposition that the interpretive nature of regulations is not an absolute bar to review. We do not believe, however, that the decision can properly be read (as Professor Jaffe warned that it might) as holding "that *a regulation of any agency is as such reviewable* as against a claim that it is not ripe." *Jaffe*, 407 [emphasis in original]. The fact that *Frozen Food* was not intended to throw open the courts to premature challenges to administrative action is shown by the Court's careful distinction of *United States* v. *Los Angeles & Salt Lake R. Co.*, 273 U.S. 299 (see 351

U.S. at 43–44). *Frozen Food* holds only that where all other elements of "ripeness" are present, the fact that regulations are interpretive will not necessarily preclude early review."

III

THE REGULATIONS CORRECTLY INTERPRET THE STATUTE AND SHOULD BE SUSTAINED IN THE EVENT THAT THIS COURT REACHES THAT ISSUE

If the Court rejects the arguments we have presented above and holds that review of the validity of these regulations at the present juncture is permitted by the Food, Drug and Cosmetic Act and that the issue is presently ripe for judicial consideration, we believe it would be appropriate for the Court to reach the merits and pass on the validity of the regulations. Our reasons for suggesting this course are the following: The record is complete if no factual development is required; the issue is purely legal and requires no weighing of testimony or other evidence; the district court reached and decided the question; and the action

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[20] The courts of appeals which have had occasion to apply and construe *Frozen Food* in a variety of factual circumstances have not given it an open-ended effect. See, *e.g.*, *Continental Bank and Trust Company* v. *Martin*, 303 F. 2d 214, 217 (C.A.D.C.); (holding an order of the Federal Reserve Board not subject to early review); *National Van Lines, Inc.* v. *United States*, 326 F. 2d 362, 367 (C.A. 7) (holding tariff orders of the Interstate Commerce Commission reviewable where the orders were issued because of the "admittedly inadvertent omission of a footnote to a tariff"); *Trans World Airlines, Inc.* v. *C.A.B.*, 339 F. 2d 56, 63 (C.A. 2), certiorari denied, *sub nom. Hughes Tool Co.* v. *Trans World Airlines, Inc.*, 382 U.S. 842 (holding a C.A.B. order subject to review where it "made an authoritative pronouncement on which important transactions are likely to depend.")

is already three years old and is likely to be much older before it is finally resolved if this Court were to remand the case to the court of appeals. Since the question would be purely one of statutory construction and it concerns nearly all of the drug industry, it is not unlikely that however the court of appeals resolves the underlying issue the case will once again appear in this Court. There is a public interest in enforcing the regulations if they be valid, and we therefore urge the Court not to defer resolution of that question.

On the merits, we believe that the regulations correctly implement the legislative purpose expressed in Sections 502(e)(1)(B) and 502(n)(1) of the Drug Amendments of 1962, 21 U.S.C. 352(e)(1)(B) and 352(n)(1) (pp. 68–69, *infra*).

1. The text of the statute supports the administrative interpretation embodied in the challenged regulations. Section 502(e)(1)(B) [27] of the Act provides that a drug is to be deemed misbranded unless

> (B) for *any* prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on *any* labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for *any* proprietary name or designation for such drug or ingredient:
>
> * * * * *
>
> and *Provided*, That to the extent that compliance with * * * clause (B) of this subpara-

[27] Section 502(n)(1) relating to drug advertising—the other statutory provision involved here—uses the same pattern of language and our argument of Congressional intent applies equally to it. We focus on 502(e)(1)(B) simply because it is that section upon which the legislative history centered.

graph is impracticable, exemptions shall be established by regulations promulgated by the Secretary [emphasis added].

By requiring that the type be at least half as large as that used for "any" proprietary name Congress was necessarily directing that the established name appear every time that the proprietary name appears. For if the statute were satisfied by one or two appearances of the established name on every label or promotional piece, the word "any" would be totally confusing. Would it mean that the established name was to appear in type half the size of the *largest* proprietary name or half the size of the *smallest*? Or would it mean what Congress could plainly not have intended—*i.e.*, that the drug manufacturer could select *any* proprietary name on the label, including the very smallest one, and print the established name in type half that size?

We submit that Congress intended that the word "any" carry the same meaning throughout the statutory provision. Section 502(e)(1)(B) applies to "any" prescription drug—plainly meaning "all" prescription drugs. It covers "any" labeling—again obviously directed to "all" labeling. And it commands that the established name appear in at least half the size of "any" proprietary name—that is a reference, we submit, to "all" proprietary names appearing on the labeling. Cf. *United States* v. *Gertz*, 249 F. 2d 662, 665 (C.A. 9).

There is no substance to the district court's suggestion that the statutory requirement that the established name appear "prominently" would be super-

fluous if the statute itself contemplated an "every time" obligation (R. 54). For even if the "every time" requirement is met, it is still possible for the established name to be printed in such a fashion as to be illegible or unnoticeable. It could, for example, appear in light ink, or a label might be designed which would obscure it by superimposing portions of a design, drawing or photograph over every appearance of the established name. Or, indeed, the type on the label, including the proprietary name, might be so small that type half the size would be almost illegible. It was to insure against the ingenuity of advertising and layout designers that Congress also required that the established name be "prominent."

2. The legislative history plainly supports the Food and Drug Administration's interpretation. As originally approved by the Senate Judiciary Committee, the provisions here involved were not a part of the bill. Instead, the proposed draft contained only the requirement that the established name of any drug appear on the label under the standard of Section 502(c), 21 U.S.C. 352(c), as enacted in 1938—*i.e.*, "prominently." Upon reconsideration, the committee reported a bill which contained the language here involved. This report stated (S. Rept. No. 1744, Part 2, 87th Cong., 2d Sess., p. 8; emphasis added):

> The substitute committee amendment * * * would require that the label bear the "established" name of the drug and the established name of each active ingredient * * *. It would also require that on labels and on any labeling, *wherever* a trade or brand name is used, the established name, as defined in this section,

must be shown in type at least one-half as large as that used for the trade or brand name.

The bill reported by the House Committee on Interstate and Foreign Commerce (H.R. 11581) was similar to the Senate recommendation insofar as it required that the established name be printed on the label "in type at least half as large as that used thereon for any proprietary name * * *." It differed from the Senate version, however, in that it contained no similar requirement as to "labeling."[28] 108 Cong. Rec. 21076. Thereafter, Congressman O'Brien offered an amendment on the House floor which brought labeling within the scope of the Act. It was weaker than the Senate draft, however, in that it required the appearance of the established name on labeling only once or twice—"at the first place, and at the most conspicuous place if other than the first place" where the trade name was used. The House approved the amendment in this form. 108 Cong. Rec. 21081.

This difference between the House and Senate bills was thereafter resolved in favor of the Senate version. See H. Rep. No. 2526, 87th Cong., 2d Sess., Statement of the Managers on the Part of the House, pp. 23–24. The significance of this Conference Report was explained in the Senate by Senator Kefauver—the leading sponsor of the legislation—as follows (108 Cong. Rec. 22039; emphasis added):

[28] "Labeling" is defined in Section 201(m), 21 U.S.C. 321(m), to include all "other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

> In this section both the Senate and House versions were identical with one exception. This was a limitation upon the frequency with which the established name should appear in labeling, which among other things includes direct mail advertisements, brochures, pamphlets, and so forth; under the limitation the established name would have had to be printed only "at the first place, and at the most conspicuous place if other than the first place, at which such proprietary name for such drug or ingredient, as the case may be, is used." This limitation was not accepted by the conferees. *Thus the established name of a prescription drug must appear in type at least half as large as the trade name wherever the latter is used in drug promotional matter, including package inserts, and so forth.*

The word "wherever" in both the Senate report and in Senator Kefauver's remarks demonstrates conclusively, we submit, that the sponsors of the legislation contemplated that every appearance of the proprietary name on labels or labeling would have to be accompanied, in type at least half the size, by the established name of the drug. That this was the intention of those who were interested in the legislation was reaffirmed by Congressman O'Brien who, during hearings before a recent House committee, observed that the "every time" regulations properly reflected the results of the Conference Committee's deliberations. See Hearings Before a Subcommittee of the House Committee on Interstate and Foreign Commerce on H.R. 2410, 89th Cong., 1st Sess. (1963), pp. 297–298.

Petitioners' assertion that the regulation imposes an unreasonable hardship is patently unsound. It was Congress' intention to encourage physicians to think of prescription drugs in terms of their established names, not by the brand names which the drug companies attached to their products. As Senator Hart, one of the legislation's sponsors, put it (108 Cong. Rec. 17383):

> This bill recognizes the transcendent importance of generic names if the American people are to have good drugs at reasonable prices, and it seeks to end the failure to disclose generic names, whether that failure is intentional or unintentional.

This course was deemed necessary by Congress to achieve the result which it felt the nation's consumers were entitled to—realistic prices for drugs.[29] To achieve this end Congress could, for example, have prohibited the use of brand names (as distinguished from manufacturers' names) altogether on labels or labeling; instead it chose to associate the generic name with the brand name selected by the manufacturers. We submit that a most reasonable way to foster the mental association which Congress wished to promote is by the "every time" requirement of these regulations.

Moreover, this case involves a "contemporaneous construction of the Act by the agency entrusted with

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[29] It was brought out in the congressional debates that drugs could be purchased under their generic names at one-third or one-half the price of the same drug sold under a trade name. See 108 Cong. Rec. 17367–17368, 17381–17383. See also the views of Senators Kefauver, Dodd, Carroll, Hart, and Long, pp. 33–36, 38–39, 46–51, S. Rept. 1744, Part I, 87th Cong., 2d Sess. (1962).

its administration." *Federal Housing Administration* v. *The Darlington, Inc.*, 358 U.S. 84, 90. Cf. *Consolo* v. *Federal Maritime Commission*, 383 U.S. 607, 621. Whatever weight that construction might be given in the abstract is underscored when, as here, a basis for the challenge is that it imposes a severe burden on the industry and renders its labels illegible. The Food and Drug Administration is in constant touch with the drug industry and it is better able to judge than the courts whether there is substance to such claims. In the present case it promulgated these regulations after public proceedings, and they are substantially supported by the legislative history and purpose of the statute.

IV

VENUE WAS IMPROPER AS TO TWENTY-SIX CORPORATE PLAINTIFFS NOT INCORPORATED IN DELAWARE

The remaining issue in this case concerns the scope of the venue provisions of 28 U.S.C. 1391(e)(4) (pp. 72–73, *infra*). The finding of both courts below that venue was improper as to certain plaintiffs was, we submit, entirely correct. It accorded with the settled rule that unless Congress manifests a clear intent to the contrary, the "residence" of a corporation for venue purposes is the place of its incorporation. *Federal Power Commission* v. *Texaco, Inc.*, 377 U.S. 33, 37–39; cf. *Suttle* v. *Reich Brothers Construction Co.*, 333 U.S. 163, 166. There is no persuasive evidence, we submit, that a contrary intent has ever been manifested by Congress for purposes of Section 1391(e)(4)—*i.e.*, when the corporation is a plaintiff.

The core of petitioner's argument (Pet. Br. 40–46)—and that of the authorities which they cite—is that when Congress in 1948 revised the venue provisions of 28 U.S.C. 1391(c) as to corporate defendants, it also intended the same result as to corporate plaintiffs. Section 1391(c) provides that a corporate defendant is suable not only in the judicial district where it is incorporated but also where it is "licensed to do business or is doing business." It then concludes "and such judicial district shall be regarded as the residence of such corporation for venue purposes." Some courts have said that this latter clause would be meaningless if it were not construed as changing the venue rules as to corporate plaintiffs. See, *e.g.*, *Freiday* v. *Cowden*, 83 F. Supp. 516, 517–518 (S.D.N.Y.); *Southern Paperboard Corporation* v. *United States*, 127 F. Supp. 649, 650 (S.D.N.Y.).

The more authoritative [30] and, we believe, the better reasoned authority is that no such broad reading of Section 1391(c) is justified. The words used in the second clause are restrictive; they refer to "such" corporations not to "all" or "any" corporations, and they appear to relate back to the first clause, which plainly covers only corporate defendants. Nor, given the historical framework, does our reading render the second clause meaningless. In 1939, this Court amelio-

[30] The only courts of appeals which considered the scope of 1391(c) have agreed with the courts below and held that it refers only to the venue of corporate defendants. *Robert E. Lee & Co.* v. *Veatch*, 301 F. 2d 434 (C.A. 4), certiorari denied, 371 U.S. 813; *Carter-Beveridge Drilling Co.* v. *Hughes*, 323 F. 2d 417 (C.A. 5); cf. *Lumbermens Mut. Cas. Co.* v. *South Portland Engineering Co.*, 252 F. Supp 149 (S.D.N.Y.).

rated the rigors of the rule that corporations could be sued only in the State and judicial district in which they were chartered by holding that this requirement was waived when a corporation appointed an agent to receive service of process in the State and district in which it was doing business. *Neirbo Co.* v. *Bethlehem Shipbuilding Corp.*, 308 U.S. 165. However, on the eve of the 1948 revision of Title 28, this Court limited the waiver doctrine by holding that it did not apply in a suit against multiple defendants (one of which was a corporation) where venue as to non-resident defendants rested on the corporation's "residence" in that district. *Suttle* v. *Reich Brothers Construction Co.*, 333 U.S. 163. The second clause of Section 1391(c) was clearly intended to change the result in *Suttle*. See *Robert E. Lee & Co.* v. *Veatch*, 301 F. 2d 434 (C.A. 4), certiorari denied, 371 U.S. 813. As an authoritative commentator put it, the second "clause serves a purpose in laying venue, in a transitory action, in defendant's [corporation's] district where there are multiple defendants residing in different districts of the same state; and also in the case where defendants reside in different divisions of the same district or different districts in the same state." 1 *Moore's Federal Practice* (2d ed. 1964) 1503.

Moreover there is no indication in the history of 28 U.S.C. 1391(e) that Congress would have wanted to change the residence limitations as to plaintiff corporations[21] for purposes of the suits covered by this pro-

[21] "The principal demand for this proposed legislation comes from those who wish to seek review of decisions relating to public lands, such as the awarding of oil and gas leases, consideration

vision, as it had previously done under 1391(e) with respect to corporate defendants. The necessary consequence of petitioners' position is to authorize "forum-shopping" for no legitimate purpose. Congress never intended to permit that result.

CONCLUSION

For the foregoing reasons it is respectfully submitted that the judgment of the court of appeals should be affirmed.

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NOVEMBER 1966.

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of land patent applications and the granting of grazing rights or other interests in the public domain." S. Rep. No. 1992, to accompany H.R. 1960, 87th Cong., 2d Sess., p. 6; H. Rep. No. 536, to accompany H.R. 1960, 87th Cong, 1st Sess., p. 3. Both reports also refer to congestion in the District of Columbia which, prior to the amendment, was the only district where a case such as this could have been brought.

APPENDIX

The Federal Declaratory Judgments Act, 28 U.S.C. 2201, provides, in pertinent part:

> CREATION OF REMEDY.
>
> In a case of actual controversy within its jurisdiction, except with respect to Federal taxes, any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. * * *

Section 10 of the Administrative Procedure Act, 60 Stat. 243, 5 U.S.C. 1009, now recodified as 5 U.S.C. 701–704 (Public Law 89–554, 80 Stat. 378), provides in pertinent part:

> (a) This chapter applies, according to the provisions thereof, except to the extent that—
>
> (1) statutes preclude judicial review, or
>
> (2) agency action is committed to agency discretion by law.
>
> * * * * * * *
>
> § 702. RIGHT OF REVIEW
>
> A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.
>
> § 703. FORM AND VENUE OF PROCEEDING
>
> The form of proceeding for judicial review is the special statutory review proceeding relevant to the subject matter in a court specified by statute or, in the absence or inadequacy thereof, any applicable form of legal action, including actions for declaratory judgments

or writs of prohibitory or mandatory injunction or habeas corpus, in a court of competent jurisdiction. Except to the extent that prior, adequate, and exclusive opportunity for judicial review is provided by law, agency action is subject to judicial review in civil or criminal proceedings for judicial enforcement.

§ 704. ACTIONS REVIEWABLE

Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review. A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section whether or not there has been presented or determined an application for a declaratory order, for any form of reconsideration, or, unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative, or an appeal to superior agency authority.

Section 502 of the Federal Food, Drug and Cosmetic Act, as amended, 76 Stat. 780, 790, 21 U.S.C. 352, provides in pertinent part:

Section 502. A drug or device shall be deemed to be misbranded—* * *

(e) * * *

(1) If it is a drug unless * * *

(B) for any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling in which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient: *Provided,* That to the extent

that compliance with the requirements of clause * * *

(B) of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

* * * * *

(n) In the case of any prescription drug * * * the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name as defined in section 502(e), printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula * * *, and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with the procedure specified in section 701 (e) * * *.

Section 701 of the Federal Food, Drug and Cosmetic Act, as amended, 74 Stat. 398, 21 U.S.C. 371, provides, in pertinent part:

SEC. 701. REGULATIONS AND HEARINGS.

(a) Authority to promulgate regulations.

The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary.

* * * * * *

(e) Procedure for establishment.

(1) Any action for the issuance, amendment, or repeal of any regulation under section 401, 403(j), 404(a), 406, 501(b), or 502 (d) or (h) of this title shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefore, filed with the

Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2) of this subsection, the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) of this subsection is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3) of this subsection, the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such ob-

jections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

(f) Review of order.

(1) In a case of actual controversy as to the validity of any order under subsection (e) of this section, any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record of the proceedings on which the Secretary based his order, as provided in section 2112 of Title 28.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his

findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Secretary refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action, with respect to such regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in sections 346 and 347 of Title 28.

(5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

28 U.S.C. 1391(e) provides in pertinent part:

§ 1391. VENUE GENERALLY.

* * * * * *

(e) A civil action in which each defendant is an officer or employee of the United States or any agency thereof acting in his official capacity or under color of legal authority, or an agency of the United States, may, except as otherwise provided by law, be brought in any judicial dis-

trict in which: (1) a defendant in the action resides, or (2) the cause of action arose, or (3) any real property involved in the action is situated, or (4) the plaintiff resides if no real property is involved in the action.

Title 21 of the Code of Federal Regulations provides in pertinent part:

21 C.F.R. 1.104(g)(1)

If the label or labeling of a prescription drug bears a proprietary name or designation for the drug or any ingredient thereof, the established name, if such there be, corresponding to such proprietary name or designation, shall accompany each appearance of such proprietary name or designation. The established name shall be placed in direct conjunction with the proprietary name or designation, and the relationship between the proprietary name or designation and the established name shall be made clear by use of a phrase such as "brand of," preceding the established name, or by brackets surrounding the established name.

(2) The established name shall be printed in letters that are at least half as large as * * *.

* * * * *

21 C.F.R. 1.105(b)(1)

If an advertisement for a prescription drug bears a proprietary name or designation for the drug or any ingredient thereof, the established name, if such there be, corresponding to such proprietary name or designation, shall accompany each appearance of such proprietary name or designation. The established name shall be placed in direct conjunction with the proprietary name or designation, and the relationship between the proprietary name or designation and the established name shall be made clear by use of a phrase such as "brand of," preceding the established name, or by brackets surrounding the established name.

(2) The established name shall be printed in letters that are at least half as large as the letters comprising the proprietary name or designation with which it is joined, and the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, layout, contrast, and other printing features.

U.S. GOVERNMENT PRINTING OFFICE: 1988

SUPREME COURT, No. 59

DEC 27 1966

JOHN F. DAVIS, CLERK

Supreme Court of the United States

OCTOBER TERM, 1966

ABBOTT LABORATORIES, ET AL., *Petitioners*,

v.

JOHN W. GARDNER, Secretary of Health, Education, and Welfare, and JAMES L. GODDARD, Commissioner of Food and Drugs, *Respondents*.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

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Supreme Court of the United States

OCTOBER TERM, 1966

No. 39

ABBOTT LABORATORIES, ET AL., *Petitioners,*

v.

JOHN W. GARDNER, Secretary of Health, Education, and Welfare, and JAMES L. GODDARD, Commissioner of Food and Drugs, *Respondents.*

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

REPLY BRIEF FOR PETITIONERS

Respondents continue their attempt to deprive petitioners of a fundamental right recognized as long ago as *Philadelphia Co.* v. *Stimson,* 223 U. S. 605 (1912)—the right to challenge in the Federal courts the legality of official actions vitally affecting petitioners' businesses. Respondents urge that petitioners should be required to operate their businesses under a cloud, acting at their peril in violating the regulations involved in this case, and awaiting respondents' decision to enforce the regulations somewhere in some manner against somebody at some time. An entire industry, respondents suggest, cannot have its day in court to determine whether respondents' regulations are unlawful and then proceed under an established rule of law equally applicable to all its members.

This result is directly contrary to the purpose of Congress in enacting the Declaratory Judgment Act. (See Pet. Br. 15-16.) It cannot be supported in common sense, for it is neither practical nor equitable. The validity of the regulations may be reviewed in an action of this kind. Indeed, respondents themselves, when they back away from the pro-

cedural obstacles they have concocted, ask this Court to pass on the issue presented by the cross-motions for summary judgment because it

> "is purely legal and requires no weighing of testimony or other evidence; the district court reached and decided the question; . . . the question would be purely one of statutory construction and it concerns nearly all of the drug industry. . . ."

At this point they urge that "there is a public interest in enforcing the regulations if they be valid. . . ." (Res. Br. 55-56). Petitioners would add that there is also a public interest in preventing enforcement of the regulations if they are invalid, and that it is for these reasons among others that the District Court was correct in holding that the action presented a ripe, justiciable issue.

Petitioners will first reply to respondents' efforts to bar the courts to petitioners.[1] Thereafter, so that petitioners' position on the merits will be before the Court should it determine to decide the merits rather than to remand the case to the Court of Appeals, petitioners will deal with respondents' contention that the regulations are not invalid.

I. THE REGULATIONS ARE REVIEWABLE IN THIS ACTION

Petitioners' main brief (pp. 23-40) pointed out the errors committed by the Court of Appeals, and respondents do not even attempt to defend that Court's reasoning Respondents disown the Court of Appeals' decision and advance new theories in an effort to prevent a decision as to the validity of the regulations. These new theories are as erroneous as those advanced by the Court of Appeals.

[1] As to the venue issue in this case, no new contention not anticipated in petitioners' main brief (pp. 40-46) has been advanced by respondents, and nothing further need be said on that issue in this brief.

A. The Regulations Are Ripe for Review

Respondents concede (Res. Br. 46) that "the regulations involved in the present case are the product of mature administrative judgment, and are not merely preliminary or tentative agency conclusions." But in an effort to avoid the problem presented for them by the finality of the regulations, respondents say that enforcement of the regulations is in the hands of the Justice Department and for this reason they have "a preliminary cast." (Res. Br. 47 n.23). Certainly, if respondents and the Department of Justice were at loggerheads on the regulations, with the Department taking the position that it would not enforce them and would support anyone suing to enjoin their administrative enforcement by respondents, this might warrant a refusal to hold the regulations ripe for review. But this has not happened here. Respondents have been represented by the Justice Department in this case from its inception, and continue to be so represented in this Court, and, except for the Department here disowning some of the arguments made by respondents below, there has never been even a hint of anything but close harmony between respondents and the Department of Justice. Indeed, respondents' brief specifically negates any suggestion that the Attorney General would refuse to enforce the regulations. (Res. Br. 47 n.23).

Further, respondents' argument would make sense only if the Department of Justice had the *sole enforcement* authority, but this is not the case here, for respondents can also enforce the regulations.[2] Respondents in effect admit

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[2]Unlike the situation here, in neither Ewing v. Mytinger & Casselberry, Inc., 339 U. S. 594 (1950), nor Helco Prods. Co. v. McNutt, 137 F. 2d 681 (D. C. Cir. 1943), was there any indication that the agency had any *independent* enforcement authority with respect to the action there challenged. In each case, the agency could only recommend enforcement to the Department of Justice and could not enforce

(Res. Br. 36 n.14, 41) that they will not clear for initial marketing drugs whose labels and labeling material do not comply with the regulations and will not permit the marketing of antibiotics not complying with the regulations. The suggestion that petitioners should simply violate the regulations and wait until they are sued, suffering without complaint administrative action which keeps safe and effective new products off the market, is irresponsible.

Under the statute, moreover, both criminal and civil sanctions are specified if the regulations are violated. These are severe. Petitioners would be subject to criminal prosecutions (21 U. S. C. § 333), to seizure proceedings (21 U. S. C. § 334), and to injunction actions (21 U. S. C. § 332).[8]

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its actions on its own. In any event, compare the later view of the District of Columbia Circuit in FTC v. Nash-Finch Co., 288 F. 2d 407 (D. C. Cir. 1961), where the Court upheld a challenge in a declaratory judgment action to an FTC ruling even though enforcement was only in the hands of the Department of Justice. The Court adopted the common-sense approach that the interests of the Justice Department could obviously be adequately represented in the suit against the agency.

[8]Petitioners are aware of respondents' representations as to the "policy" and "intention" of the Food and Drug Administration and that the Justice Department "will proceed only civilly" to enforce these regulations. (Res. Br. 41 and n.19). These representations, however, do not affect this case. First, it must be noted that the so-called "policy" of the FDA (and presumably the Justice Department) not to seek criminal sanctions when the underlying statute is subject to different readings has apparently not filtered down to the ranks of the FDA and the United States Attorneys, as the following recent criminal actions indicate. United States v. Abbott Laboratories, 66 CR. 584, N. D. Ill., information filed Sept. 19, 1966; United States v. The Upjohn Co., No. 7503, W. D. Mich., information filed Aug. 23, 1966.

Moreover, it is quite clear that even if the regulations could be enforced only administratively, this would suffice to render them ripe for review. Columbia Broadcasting System, Inc. v. United States, 316 U. S. 407 (1942); United States v. Storer Broadcasting Co., 351 U. S. 192 (1956). Indeed, even an agency's willingness to arrange a test case to determine the validity of regulations—and respondents' representations are a far cry from that—is not suffi-

This case is thus precisely the same as *Frozen Food Express* v. *United States*, 351 U. S. 40 (1956), where regulations having "an immediate and practical impact" on private parties and enforceable either administratively or through court proceedings brought by the Department of Justice were held ripe for review. 351 U. S. at 43-44.[4] The fact that a decision there as to the validity of the regulations could have been obtained either in the administrative or court enforcement proceeding did not require the industry to wait until either type of proceeding was brought before challenging the regulations. See also *Columbia Broadcasting* and *Storer, supra*, and the Second Circuit's reading of these landmark cases in *Toilet Goods Ass'n*, 360 F. 2d 677, 685-86.[5]

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cient to preclude a direct challenge to regulations vitally affecting private interests. *Columbia Broadcasting, supra.* (See Res. Br. 52.)

Finally, belated representations to this Court cannot affect the question of whether the District Court was correct in holding the regulations ripe for review. *Cf.* American Life Ins. Co. v. Stewart, 300 U. S. 203, 215 (1937); Spector Motor Service, Inc. v. O'Connor, 340 U. S. 602, 605 (1951).

[4]Even the ICC's invitation to the Court in that case to decide the merits (see Res. Br. 54) is echoed in the statement of the FDA Commissioner at the time this suit was instituted that FDA welcomed actions challenging their regulations. (See Pet. Br. 13.)

[5]Respondents also mention the provision in § 502(e)(1)(B) of the Act, 21 U. S. C. § 352(e)(1)(B), for exemptions from the requirements of that section where compliance would be "impracticable". This provision, however, contemplates exemptions in individual situations, not where an entire industry challenges the legality of the "every time" requirement imposed by the respondents. In any event, as respondents acknowledge (Res. Br. 48 n. 24), the exemption provision applies only to the section of the regulations dealing with labeling and does not apply to the advertising section, the legality of which was also challenged in this action. See United States v. Storer Broadcasting Co., 351 U. S. 192 (1956) (regulation as to which waivers could be granted by FCC held ripe for review); United Gas Pipe Line Co. v. FPC, 181 F. 2d 796, 799-80 (D. C. Cir. 1950), *cert. denied*, 340 U. S. 827 (1950) ("if [exception from regulations] . . . furnishes only a partial remedy, or no remedy at all, . . . the proper forum is the district court"); 3 Davis, *Administrative Law* § 20.07 (1958).

Whether or not respondents are correct that "usually" the validity of regulations depends on factual variables (Res. Br. 49), respondents agree that in this case "the issue is purely legal and requires no weighing of testimony or other evidence" and that "the question would be purely one of statutory construction. . . ." (Res. Br. 55-56.) This purely legal issue, arising on cross-motions for summary judgment, is obviously an appropriate one for court review now. There certainly was no need for an inquiry into any factual issue in order for the District Court to determine whether the regulations are valid.

Of course, the District Court did not, after declaring these regulations invalid, go on to tell respondents what new regulations, if any, they should write. That is for the agency to determine; it, not the District Court, has the responsibility of administering the statute. All that any court can properly do is determine whether particular agency action is valid or invalid, not what further action, if any, the agency could or should take. *Cf. FPC* v. *Idaho Power Co.*, 344 U. S. 17, 20 (1952) ("function of the reviewing court ends when an error of law is laid bare"). Any asserted lack of "guidance" (Res. Br. 51) from the District Court's decision is thus no basis for saying that the issue presented was not appropriate for resolution by the District Court.[6]

The issue was and is clear-cut—whether respondents had statutory authority to promulgate regulations that a drug's established name must be repeated every time the drug's proprietary name is mentioned. In promulgating the regulations, respondents did not look at every piece of promotional material; under their view, this would be unnecessary because they claim that legislative history compelled their interpretation. Similarly, as the District Court noted (R. 40), there was no reason for it to make an individu-

[6]It is far from idle speculation to suggest that had the District Court attempted to issue some guidance to the respondents, respondents would probably be complaining of improper judicial intrusion into an area of their primary responsibility.

alized determination of the validity of the regulations as to each promotional piece.

The regulations represent an across-the-board determination which was invalidated by the District Court because the statute does not require an "every time" repetition of a drug's established name. The statute's requirements, the District Court determined, are couched in terms of prominence, rather than frequency of appearance, of the drug's established name.[7] The regulations were thus properly declared to be invalid. Of course, as respondents argue (Res. Br. 31-35), life would be easier for them if no court could ever declare regulations such as these invalid in this type of action. But respondents are not free to do as they please in administering the statute. Congress has set boundaries within which respondents must stay; it is the courts' function to see that these boundaries are respected by the respondents.

In short, the issue presented is the proper construction of a Federal statute, an issue that is clearly within the competence of Federal District Courts to decide. The issue was appropriately decided in this action since no relevant factual variables would be presented in any enforcement action. The District Court was as fully informed on this issue as would be any court in any future enforcement proceeding.

B. Congress Did Not Intend To Preclude Preenforcement Review of Any Regulations

Respondents have not met the burden of demonstrating that Congress intended to prohibit Federal courts from de-

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[7] This is also petitioners' view of the statute, and there has been no inconsistency in petitioners' position. Petitioners recognize that on some items—a multi-page product brochure, for example—the statutory requirement of "prominence" might call for more than one mention of the drug's established name. Petitioners so acknowledged in the District Court and have not departed from this position. Despite respondents' assertions (Res. Br. 30), there is nothing to the contrary in petitioners' brief in the Court of Appeals or in the petition for writ of certiorari.

termining in this type of litigation the legality of the regulations, an issue that is ripe for decision and wholly appropriate for judicial resolution.

Respondents do not argue that the statute itself, by its terms, precludes review of these regulations. Respondents rely exclusively on legislative history. The most that respondents can say about the legislative history, however, is that Congress "must have acted on the premise" (Res. Br. 6) and "must have assumed" (Res. Br. 22) that review of so-called "interpretive" regulations would not be available. Respondents' theories about what Congress "must have" done—not what it in fact did—cannot be said to be the required "clear and convincing evidence" of congressional intent to preclude review. See *Heikkila* v. *Barber*, 345 U. S. 229, 232 (1953) (quoting House Report on the Administrative Procedure Act); *Rusk* v. *Cort*, 369 U. S. 367, 379-80 (1962).

On the contrary, both the statute and its legislative history are clear that Congress in 1938 intended its specification of the availability of review of certain "legislative" regulations to be an additional remedy in the case of the specified regulations and not an implied preclusion of traditional equity actions and actions under the then recently enacted Declaratory Judgment Act to challenge the legality of other regulations.

a. The Statute

Section 701(f)(6) of the Act, 21 U. S. C. § 371(f)(6), specifies that "the remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law." The House Report stated that this provision

> "saved as a method to review a regulation placed in effect by the Secretary whatever rights exist to

> initiate a historical proceeding in equity to enjoin the enforcement of the regulation, and whatever rights exist to initiate a declaratory judgment proceeding." H. R. Rep. No. 2139, 75th Cong., 3d Sess. 11 (1938), *Dunn* 825.[8]

There is nothing in the legislative history cited by respondents that even suggests that Congress had any different view of the "savings" clause in Section 701(f)(6).

Respondents, however, urge a "limited construction" (Res. Br. 27) of Section 701(f)(6)—that, contrary to its language and legislative history, Section 701(f)(6) applies only where review under Section 701(f)(1) is unavailable for the "legislative" regulations made reviewable under that section. Respondents advance two reasons. First, because earlier drafts did not explicitly preserve the right to institute equity and declaratory judgment proceedings, respondents say that Congress "viewed these rights narrowly." (Res. Br. 27). On the contrary, the fact that Congress thought it necessary, at a late stage in its consideration of the bill, specifically to preserve these rights shows that Congress was greatly concerned that the Act not be read to destroy the traditional rights of an industry which would be vitally affected by unlawful regulations.

Second, respondents note that the "savings" clause by its terms applies only to the judicial review provision specified in the Act. (Res. Br. 26-27). This is precisely the point. Congress provided in Section 701(f)(6) that the judicial review specified in the Act is "in addition to and not in substitution for" other remedies. Given this clear and unequivocal statement, it can hardly be contended that Congress intended the judicial review provision to operate also as an

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[8]The reference is to Dunn, *Federal Food, Drug, and Cosmetic Act* (1938), which contains the full legislative history of the 1938 Act.

implied limitation of judicial review, as respondents would have this Court hold.

b. The Legislative History

Despite respondents' assertions, the legislative history of the 1938 Act shows clearly that Congress contemplated that traditional judicial remedies would continue to be available in the case of *all* FDA regulations, and that Congress *added* to these remedies a statutory judicial review provision applicable to certain "legislative" regulations. This is demonstrated even by the legislative history materials relied upon by respondents which will be examined in turn.[9]

1. The "Tugwell bill" (S. 1944, 73d Cong., 1st Sess. (1933), *Dunn* 37-50), as respondents note (Res. Br. 12), authorized the adoption of regulations but made no specific provision for judicial review, and respondents apparently would have this Court infer that judicial review would have been unavailable. This is not the case. Senator Copeland, who introduced this bill (see *Dunn* 37), stated with respect to it, "There was no provision for review *except such as might come under the common law;* there was no

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[9]Respondents in their discussion of legislative history rely on Ewing v. Mytinger & Casselberry, Inc., 339 U. S. 594 (1950). (Res. Br. 24-26). What light a 1950 decision of this Court sheds on the intent of the Congress in 1938 is never explained, and respondents do not contend that this decision was brought to the attention of subsequent Congresses. In any event, in *Mytinger* this Court held that an FDA finding of "probable cause," made without a hearing, on the basis of which multiple seizures were instituted by the Justice Department, was not reviewable in a declaratory judgment action. The Court said that this finding, which the Court analogized to an indictment, represented a preliminary step in the initiation of judicial proceedings in which the company would be fully heard.

No preliminary finding of the FDA is involved in this case. Involved here are mandatory regulations, formally adopted and published, the validity of which presents an issue that is wholly appropriate for judicial resolution.

direct provision made for review." 78 Cong. Rec. 8958 (1934), *Dunn* 157. (Emphasis added.) Thus, even in the earliest version of the 1938 Act, it was recognized that any "common law" rights of judicial review were preserved.

2. Judicial review provisions were included in two successor bills (S. 2000, 73d Cong., 2d Sess. § 23 (1934), *Dunn* 66; S. 2800, 73d Cong., 2d Sess. § 23 (1934), *Dunn* 86). Senator Copeland explained that this was done because of fears that "common law" judicial review might be inadequate. 78 Cong. Rec. 8958-59 (1934), *Dunn* 157-59. Respondents never explain what bearing this has on the question of congressional intent to preclude review.

3. Respondents recite that a similar judicial review provision was included in S. 5, 74th Cong., 1st Sess. § 702 (1935), *Dunn* 200, which was reported by the Senate Commerce Committee with an amendment and approved by the Senate. Again respondents do not explain how this is helpful to their theory. (See Res. Br. 13.)

4. The House Interstate and Foreign Commerce Committee deleted the judicial review provision, explaining that it felt that

> "there was no reason to *add to the existing remedies* which are applicable. . . . There is always an appropriate remedy in equity in cases where an administrative officer has exceeded his authority and there is no adequate remedy of law, and furthermore . . . ample protection is given by the so-called Declaratory Judgments Act. . . ." H. R. Rep. No. 2755, 74th Cong., 2d Sess. 9 (1936), *Dunn* 557. (Emphasis added.)

This significant demonstration of lack of intent to preclude review is glossed over by respondents who say only that the

lack of a judicial review provision was attacked on the House Floor. (Res. Br. 13). They fail to state, however, that the basis of the attack was the claim that absent a judicial review provision a person affected by regulations could under traditional remedies obtain review only of questions of law and of whether the facts found were supported by substantial evidence, but could not otherwise obtain review of the facts. 80 Cong. Rec. 10243-44 (1936), *Dunn* 593-94. There was thus recognition by both those supporting and those opposing a specific judicial review provision that, even in its absence, the equity jurisdiction of the courts would be available.[10]

5. During the next Congress, consideration was given to the bill ultimately enacted as the Federal Food, Drug, and Cosmetic Act. S. 5, 75th Cong., 1st Sess. (1937), *Dunn* 636-55. It was reported to and passed by the Senate without any discussion relevant here. (See Res. Br. 15.)

6. The House Interstate and Foreign Commerce Committee again redrafted the bill. The House Committee bill provided, as the Act does now, for judicial review of certain "legislative" regulations and also contained the "savings" clause now found in Section 701(f)(6). See *Dunn* 810-11. The House Committee's view, it has already been

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[10]This was also the view of the Department of Justice, which stated with respect to a later bill:

> "[E]ven without any express provision in the bill for court review, any citizen aggrieved by any order of the Secretary, who contends that the order is invalid, may test the legality of the order by bringing an injunction suit against the Secretary, or the head of the Bureau, under the general equity powers of the court." 83 Cong. Rec. 7892 (1938), *Dunn* 934.

While respondents mention (Res. Br. 16) the Justice Department's opposition to a specific judicial review provision, they fail to recite the above basis of that opposition, which cannot be fitted within their legislative history theory.

noted (pp. 8-9, *supra*), was that the "savings" clause operated to preserve whatever rights existed to institute equity and declaratory judgment proceedings to challenge FDA regulations. This clear and explicit statement is dismissed by respondents who say that it was not sufficiently explained. (Res. Br. 16). It is difficult to see, however, how the congressional intent to preserve the right to institute this type of action could have been more explicit.

7. As respondents point out (Res. Br. 16-17), a minority of the House Committee objected to the judicial review provision, as did the Secretary of Agriculture. H. R. Rep. No. 2139, pt. 2, 75th Cong., 3d Sess. (1938), *Dunn* 834-38. Respondents fail to point out, however, that the minority noted that the method of review provided in the bill "is in addition to, and not in substitution for, other methods of review provided by law, such as equity proceedings and proceedings under the Declaratory Judgment Act." *Id.* at 1, *Dunn* 834. The minority and the Secretary went on to object to what they viewed as a new form of judicial review which they felt went beyond existing law.[11] The same criticism was expressed on the House Floor by Congressman Mapes, who signed the minority report, in a statement cited, but understandably not quoted, by respondents (Res. Br. 17):

> "The particular provision in the bill to which I am opposed is . . . paragraph (f) of section 701: That does not mean that I am opposed to any court review. Not at all. Everyone concedes the right of an aggrieved person to a court review, or his day in court, but not such a court review as the one provided for

[11]The Court in *Toilet Goods Ass'n*, 360 F. 2d 677, 684 n.7, similarly read the minority report. It was viewed as indicating that "the special [review] procedure was understood to be an additional protection for industry and not an exclusive method of review of all actions for the benefit of the agency."

in the committee substitute." 83 Cong. Rec. 7772 (1938), *Dunn* 842.

8. Congressman Mapes, who emerged as the spokesman for those opposed to the judicial review provision reported by the House Committee, then offered an amendment designed to satisfy the objections of the Secretary of Agriculture to that provision. 83 Cong. Rec. 7891, 7892 (1938), *Dunn* 931-32, 933.[19] During the debate on his amendment, which was supported by the only other signer of the minority report who spoke to the point, 83 Cong. Rec. 7896 (1938), *Dunn* 944, Congressman Mapes repeated that:

> "[U]nder existing law any individual may go into the district court in which he resides for the purpose of obtaining an injunction against any order of the Food and Drug Administration that applies to him, that is arbitrary, capricious, unreasonable, or contrary to law, and that will cause him irreparable damage. *No one proposes to take that right away from anyone.*" 83 Cong. Rec. 7893 (1938), *Dunn* 936. (Emphasis added.)

And he said again:

> "The injunction matter is outside of both of these provisions. *The injunction remedy by any aggrieved person is had without reference to the provisions in the bill or to my amendment.*" 83 Cong. Rec. 7894 (1938), *Dunn* 938. (Emphasis added.)

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[19] Although, as respondents point out (Res. Br. 18, 31 n.13), the amendment, providing among other things for review in the Courts of Appeals instead of the District Courts, was rejected on the House Floor, 83 Cong. Rec. 7898 (1938), *Dunn* 950, respondents fail to mention that review in the Courts of Appeals was provided for in the bill as reported by the Conference Committee and as enacted. H. R. Rep. No. 2716, 75th Cong., 3d Sess. 17 (1938), *Dunn* 987.

Respondents seek to minimize the importance of these statements—bearing directly on the issue here—by noting (Res. Br. 31 n.13) that Representative Leavy said that the doctrine of sovereign immunity would bar actions against those administering the Act. 83 Cong. Rec. 7895 (1938), *Dunn* 941. Respondents fail to point out that this conclusion was disputed by Representative Sauthoff. *Ibid.* The important point here, however, is that even respondents do not say that anyone contradicted Representative Mapes' statement that neither the Committee bill nor his amendment had any effect on any person's right to obtain an injunction against FDA regulations, the position also taken in the House Report and recognized in the minority report.

9. Differences between the House and Senate bills were resolved in conference, and respondents note (Res. Br. 18) that the Conference Committee stated that "legislative" regulations would be reviewable under the Act. But the Committee did not say that other regulations would not be reviewable. And the lack of any negative implication is shown by the Committee's specific statement that there was retained in the Conference bill "the provision of the House amendment under which the remedies provided for are in addition to, and not in substitution for, other legal remedies. . . ." H.R. Rep. No. 2716, 75th Cong., 3d Sess. 25 (1938), *Dunn* 995-96.

Petitioners submit that this legislative history is crystal clear and confirms the express statutory declaration that the judicial review specified in the Act is solely an additional, non-exclusive remedy in the case of certain regulations. The legislative history shows that Congress did intend to distinguish between "legislative" regulations reviewable under Section 701(f) and other FDA regulations. But the distinction was not between reviewability of the former regulations and nonreviewablity of the latter, as respondents contend. Nowhere in the legislative history is

there even any suggestion of any intent to preclude review of any regulations. It was continually acknowledged that any FDA action could be challenged in a declaratory judgment or injunction action, if the requirements applicable to these types of proceedings were met. The distinction was between those "legislative" regulations made specifically reviewable under a special procedure in the courts of appeals and other regulations as to which the only available remedy would require satisfaction of the requirements applicable to all equity and declaratory judgment actions.[18]

The specification of judicial review in the Act is not rendered superfluous, as respondents contend, by the fact that Congress did not contemplate precluding preenforcement review of other regulations. Where regulations are not covered by a specific judicial review provision, there are many obstacles that must be overcome in order to obtain review. This case is a good example. Respondents moved to dismiss this case in the District Court, alleging four separate grounds of dismissal—the lack of an "actual controversy," failure to join an indispensable party, no review of "interpretive" regulations, sovereign immunity—as well as complaining that venue was improper for 26 petitioners. (R. 19-21.) Obstacles such as these to immediate review are eliminated in the case of regulations made reviewable under Section 701(f) of the Act. The judicial review pro-

[18]Nothing in the subsequent amendments to the Act relied upon by respondents (Res. Br. 28-30) calls for any different conclusion. These amendments, in respondents' words (Res. Br. 29), "specified the regulations which are subject to judicial review either under Section 701(f) or under specific provisions in the amendments and have been silent as to all others." Congressional silence is no evidence of any intent to preclude review. Heikkila v. Barber, 345 U. S. 229, 232 (1953). See Jaffe, *Judicial Control of Administrative Action* 357 (1965):

> "The mere fact that some acts are made reviewable should not suffice to support an implication of exclusion as to others. The right to review is too important to be excluded on such slender and indeterminate evidence of legislative intent."

vision thus serves an important function even though regulations such as those involved here are not barred *ab initio* from judicial consideration when they are promulgated.

II. THE REGULATIONS ARE WITHOUT STATUTORY BASIS

Respondents contend that the "every time" regulations are "interpretive". As such, the question on the merits can be put very simply: Does the statute require an "every time" mention of the established name? If it does not, then the regulations are invalid, for it is clear that respondents cannot, in the guise of interpreting a statute, impose a requirement not imposed by the statute itself, whether or not respondents have the proverbial "expertise" or the regulations are "reasonable". This was made clear in *FCC v. American Broadcasting Co.*, 347 U. S. 284 (1954), in which "interpretive" regulations of the FCC which prohibited the broadcasting of "give-away" programs were invalidated:

> "The question presented is whether the . . . provisions correctly interpret § 1304 of the United States Criminal Code [which] . . . prohibits the broadcasting of '. . . any lottery. . . .'
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> * * *
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> "[T]he Commission's power . . . is limited by the scope of the statute. Unless the 'give-away' programs . . . are illegal under § 1304, the Commission cannot employ the statute to make them so by agency action." 347 U. S. at 285, 290.

Here, as will be shown below, the statute cannot be read as imposing an "every time" requirement, and the legislative history does not show that Congress intended to impose this requirement.

A. The Statutory Language Precludes Respondents' Interpretation

Section 502(e)(1)(A) of the Act, 21 U. S. C. § 352 (e)(1)(A), declares a drug to be misbranded unless "its

label bears . . . the established name . . . of the drug. . . ." With respect to "any prescription drug," Section 502(e)(1)(B) of the Act requires that on labels "and on any labeling on which a name for such drug . . . is used," the established name of the drug must be "printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug. . . ." The language of Section 502(n) of the Act, 21 U. S. C. § 352(n), which applies to advertising, is similar. All advertisements for a prescription drug must include "a true statement of . . . the established name . . . printed prominently and in type at least half as large as that used for any trade or brand name thereof. . . ."

It is perfectly clear that this language, by its plain terms, does not require an "every time" repetition of a drug's established name. Had Congress intended an "every time" requirement, it could very easily have written this requirement into the statute. It did not do so. Congress required only that the established name be printed "prominently" and in type half as large as that used for "any" proprietary name. The logical reading of "any", the only possible ambiguity in the statute, is that if on a piece of labeling, for example, the proprietary name is mentioned four times, the type size of the established name must be half as large as the type size used for "any" printing of the proprietary name. In this event, the type size would have to be half as large as the largest type used in mentioning the proprietary name. "Any" also has the effect of obviating the type-size requirement where no proprietary name is printed, as well as covering the case where two or more different proprietary names appear in a single promotional piece.

Respondents suggest that "any" be read to mean "all". However, this does not help the respondents; even if "all" were substituted for "any", the respondents' interpretation would not follow, for the statute would read: The

established name must be "printed prominently and in type at least half as large as that used for *all* proprietary name[s] or designation[s]. . . ." It will be noted that even this perversion of the statutory language does not call for an "every time" repetition. It would require that if, for example, on a piece of labeling the proprietary name is mentioned four times, the established name's type size must be half as large as that used for all four mentions of the proprietary name. Congress scarcely intended this result and, in any event, it does not help the respondents.

Finally, it must be noted that the type size requirement is not the only requirement contained in the statute. The statute also requires that the established name must be printed "prominently". In light of the "prominently" requirement, which serves to bring established names to the attention of physicians, an "every time" requirement is superfluous. And, if an "every time" requirement is to be read into the statute, the requirement of "prominently" is superfluous. As the District Court determined:

> "If Congress had intended that the generic name appear every time the brand name appears there would be no reason to use the word 'prominently'. The use of the word shows Congress was concerned that the generic name appear in a conspicuous place. If the generic name appeared with every mention of the trade name the requirement of prominence would be unnecessary." (R. 54).

Thus, the argument that the "every time" requirement is contained in the statute runs counter to the most elementary principle of statutory construction, which requires that effect be given to all parts of a statute. *E.g., United States v. Menasche,* 348 U. S. 528, 538-39 (1955).[14]

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[14]Respondents' efforts to find some use for the "prominently" requirement if the statute requires an "every time" repetition of the established name are ingenious but unavailing. Respondents' sugges-

The basic difficulty with respondents' position is that the statute, which specifies criminal sanctions for its violation, requires only that the established name appear, that it appear "prominently", and that it appear in a specified size of type. No amount of tortuous verbalizations can succeed in having these statutory provisions read as dealing with the number of times the established name must appear.

B. The Legislative History Does Not Show That Congress Intended an "Every Time" Requirement

Respondents are forced to rely on legislative history in an effort to have the statute bear the interpretation which they have adopted. In doing so, they seize upon two isolated items—in fact, on two mentions of the one word "wherever" (Res. Br. 60)—in the extensive legislative history of the 1962 amendments to the statute and argue that these demonstrate conclusively that Congress intended an "every time" requirement. Even these two items, however, are directly contradicted by other items in the legislative history. Moreover, as the District Court found, there was no "general Congressional intent" to impose an "every time" requirement. (R. 55.)

a. "Wherever" in the Senate Report

The first use of the word "wherever" relied upon by respondents is in the Senate Judiciary Committee Report. The Committee Report states:

> "It [the Committee amendment] would . . . require that on labels and on any labeling, *wherever* a trade or brand name is used, the established name, as defined in this section, must be shown in type at least

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tion (Res. Br. 58) that Congress inserted the "prominently" requirement "to insure against the ingenuity of advertising and layout designers" is simply their theory. They cite no legislative history in support of this theory.

> one-half as large as that used for the trade or brand name." S. Rep. No. 1744, pt. 2, 87th Cong., 2d Sess. 8 (1962). (Emphasis added.)

By emphasizing one word in a Committee Report, which of course does not receive the same degree of attention that is devoted to drafting legislation, the respondents are grasping for straws. First, if the Report is to be construed as a statute, "wherever" must apply to its antecedents in the Report, *i.e.*, labels and labeling, and "wherever" would refer only to each label and piece of labeling. So read, "wherever" does not connote frequency of appearance on any particular item, but only requires that the established name must appear on each label and piece of labeling bearing a proprietary name.

Moreover, even if, as the respondents suggest, "wherever" in the Report should be construed as meaning "every time", this reading of "wherever" is squarely contradicted by the prepared statement of Senator Eastland, Chairman of the Senate Committee, in which he explained the bill on the Senate Floor two days after the Report was issued. Senator Eastland stated:

> "On the label, and on any labeling on which the drug . . . is named, *if* a trade name is used for the drug . . ., the established name of the drug . . . must be shown in type at least half the size of the type used for the trade name." 108 Cong. Rec. 17366-67 (1962). (Emphasis added.)

Senator Eastland's statement is similar to the language in the Senate Report, with one significant difference. Senator Eastland used the word "if" where the Senate Report used the word "wherever". Even if "wherever" can be read as meaning "every time", the word "if" certainly has no such connotation. In light of this difference between the language

in the Senate Report and that used by the Chairman of the Committee in a prepared statement on the Senate Floor, it cannot be contended that "wherever" in the Report is a compelling statement of congressional intent. See *Chicago, M., St. P. & Pac. R. R.* v. *Acme Fast Freight, Inc.*, 336 U. S. 465, 475 (1949) (Report contradicted by explanatory floor statement "can hardly be considered authoritative").

b. Senator Kefauver's "Wherever"

The other use of the word "wherever" relied upon by respondents occurred during Senator Kefauver's explanation of the Conference Committee's rejection of an amendment proposed by Congressman O'Brien, which had been adopted by the House.

As reported by the House Interstate and Foreign Commerce Committee, the bill would have amended Section 502(e) of the Act to require that

> "for any prescription drug the established name of such drug . . . on such label [must be] . . . printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug. . . ." H. R. Rep. No. 2464, 87th Cong., 2d Sess. 64 (1962).

During the debate in the House, Congressman O'Brien offered an amendment, to which no objection was noted, which made two changes in the bill as reported. The first change was to extend the requirement as to the size of the established name to labeling, since the bill applied only to a drug's label. The second change was to insert a provision that, in the case of labeling, the requirement that the established name be printed prominently and in half-size type was applicable "at the first place, and at the most conspicu-

ous place if other than the first place, at which such proprietary name for such drug . . . is used. . . ." 108 Cong. Rec. 21081 (1962).

This second aspect of the O'Brien amendment was rejected in conference. Senator Kefauver's explanation of the rejection was that the amendment

> "was a limitation upon the frequency with which the established name should appear in labeling. . . . This limitation was not accepted by the conferees. Thus the established name of a prescription drug must appear in type at least half as large as the trade name *wherever* the latter is used in drug promotional matter, including package inserts, and so forth." 108 Cong. Rec. 22039 (1962). (Emphasis added.)

Neither the rejection of the amendment nor Senator Kefauver's explanation of that rejection is any demonstration of a congressional purpose to impose an "every time" requirement.

First, the rejection of the amendment does not necessarily reflect congressional approval of the opposite of the rejected proposal. *Cf. Girouard* v. *United States*, 328 U. S. 61, 69-70 (1946); *United States* v. *South-Eastern Underwriters Ass'n*, 322 U. S. 533, 560-61 (1944); *Cleveland* v. *United States*, 329 U. S. 14, 22-23 (1946) (concurring opinion). Moreover, even if "psychoanalysis of Congress"[15] is a proper function of the judiciary and it is assumed that Congress intended the opposite of the O'Brien amendment, it does not follow that the intent of the conferees when they rejected the O'Brien amendment was to impose an "every time" requirement. "Every time" is not necessarily the "opposite" of the O'Brien amendment. Its rejection

[15] United States v. Public Util. Comm'n, 345 U. S. 295, 319 (1953) (Jackson, J., concurring).

could mean, at most, that the required mention of the established name specified in the O'Brien amendment was not necessarily sufficient, not that "every time" was imperative.

Second, so far as Senator Kefauver's statement is concerned, the District Court dealt with it correctly. The Court noted that "Kefauver's term 'wherever' is not free from ambiguity." (R. 55). That this conclusion was valid has already been discussed in connection with "wherever" as used in the Senate Report (pp. 20-21, *supra*). The Court also stated that "it is not clear that Kefauver's characterization of the O'Brien amendment as a limitation is accurate." (R. 55). This conclusion is supported by the Report of the House Managers on the Conference Committee. This Report is directly contrary to Senator Kefauver's statement as to the nature of the O'Brien amendment and, thus, as to the effect of the Conference Committee's rejection of that amendment. The House Managers stated:

> "Both the House amendment and the Senate bill in the section relating to the use of official names on the labels and the labeling of prescription drugs provided that the established name of a drug . . . must be printed on any label or labeling prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug. . . . With regard to labeling on prescription drugs the House amendment *further provided* that the established name of the drug . . . must be *so* printed at the first place and at the most conspicuous place if other than the first place, at which such proprietary name for such drug . . . is used.
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> "The Senate version did not contain the second provision with regard to labeling.
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> "The conference substitute adopts the Senate version." H. R. Rep. No. 2526, 87th Cong., 2d Sess. 23-24 (1962). (Emphasis added.)

There is no indication in this Report that the House Managers construed the O'Brien amendment as a *limitation* upon the number of times the statute would require the established name to be mentioned. On the contrary, the Report treats the provision relating to the place where the established name must appear as an *additional* requirement, one not already imposed by the bill. This view is, of course, consistent with the first aspect of the O'Brien amendment, noted above, which *extended* the bill to cover labeling. The second aspect of the amendment similarly was an extension of the bill and not a limitation as to its reach. The O'Brien amendment having been rejected in conference, the bill remained as previously reported—dealing only with the conspicuousness with which the established name must be printed and not with the number of times it must be mentioned.[16]

c. The Congressional Purpose

By no stretch of the imagination can the two mentions of the word "wherever"—the legislative history exclu-

[16]Respondents also cite Congressman O'Brien's observation during a subsequent Congress on the Conference Committee's rejection of his amendment. (Res. Br. 60.) This, however, is not part of the legislative history of the 1962 drug amendments at all since it occurred *after* the statute was passed and, indeed, *after* the proposed regulations, which incorporated an "every time" requirement, were issued. And "statutes are construed by the courts with reference to the circumstances existing at the time of the passage." United States v. Wise, 370 U. S. 405, 411 (1962). See also SEC v. Capital Gains Research Bureau, Inc., 375 U. S. 180, 199-200 (1963); United States v. Philadelphia Nat'l Bank, 374 U. S. 321, 348-49 (1963); United States v. Price, 361 U. S. 304, 313 (1960); Ramspeck v. Federal Trial Examiners Conference, 345 U. S. 128, 143 n.9 (1953); Fogarty v. United States, 340 U. S. 8, 13-14 (1950); United States v. United Mine Workers, 330 U. S. 258, 281-82 (1947). In addition, all that Congressman O'Brien said was that he was on the Conference Committee and that the Committee rejected his amendment. For reasons already noted, the rejection of that amendment does not support the respondents' contention that Congress intended an "every time" requirement.

sively relied upon by respondents—be said to demonstrate that there was a general congressional intent to impose an "every time" requirement. The lack of any such intent is shown by one simple fact: Although both Houses of Congress gave extensive consideration to the precise statutory language dealing with the required display of a drug's established name,[17] not once did any legislator say anything to the effect that "This means that the established name must be repeated each time the drug's brand name is mentioned." This is not an abstruse, difficult concept to grasp or articulate and it requires no sophisticated, subtle thinking. Certainly, if Congress had intended this "every time" requirement it could very easily have been spelled out in specific terms, if not in the statute, then at least in the

[17]The relevant language was repeatedly being changed as the various bills went through the legislative mill. As introduced by Senator Kefauver on April 12, 1961, S. 1552 required that a drug's "official name" be "printed *in type at least as large and as prominent* as that used for any trade or brand name. . . ." S. 1552, 87th Cong., 1st Sess. §§ 4(a)(4), 4(a)(7) (1961). (Emphasis added.) H. R. 11581, introduced by Congressman Harris on May 3, 1962, required that a drug's established name be "given *precedence in position* over any proprietary name . . . for such drug . . . and [be] . . . *in type at least as large and prominent* as that used for such proprietary name. . . ." H. R. 11581, 87th Cong., 2d Sess. § 112 (a)(4) (1962). (Emphasis added.) Section 9(a) of S. 1552 as reported by the Senate Judiciary Committee on July 19, 1962, required a drug's official name to be *"printed in a manner complying with subsection (c)* of this section. . . ." See S. Rep. No. 1744, 87th Cong., 2d Sess. 6 (1962). (Emphasis added.) (The reference is to § 502(c) of the Act, 21 U. S. C. § 352(c), which requires statements on labels and labeling to be "prominently placed thereon with such conspicuousness . . . and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.") Thereafter, the President suggested an amendment to S. 1552 that required a drug's official name to be "printed *prominently* and *in type at least half as large* as that used for any trade or brand name. . . ." See 108 Cong. Rec. 15697 (1962). (Emphasis added.) This language as to type size was subsequently adopted by the Senate Judiciary Committee and by the House Interstate and Foreign Commerce Committee and was enacted into law.

legislative history. The lack of any clear and explicit statement in the legislative history that "every time" was intended shows that this requirement was not contemplated by the Congress.

The legislative history does reveal, as the District Court determined (R. 53), that Congress was concerned that there be a prominent and conspicuous display of the drug's established name. This would enable physicians to become aware of a drug's established name so that, if they wished to do so, they could prescribe on that basis rather than by the drug's brand name. Congress did not, however, express any intention of forcing established names down a doctor's throat by imposing an "every time" requirement.

Senator Kefauver, for example, in introducing S. 1552, made no reference to any "every time" requirement. The purpose of the relevant provision of the bill (n.17, *supra*), he said, was "to help the physician to identify the family to which the drug belongs by showing clearly the official name of the product. . . ." 107 Cong. Rec. 5640 (1961). The same concern with nondisclosure of the established name and with the need for prominent disclosure was expressed in his minority views and those of Senators Carroll, Dodd, Hart, and Long on S. 1552 as originally reported by the Senate Judiciary Committee (see n.17, *supra*). S. Rep. No. 1744, 87th Cong., 2d Sess. 38-39, (1962). Senator Kefauver again criticized the omission or lack of conspicuousness of established names in advertisements and labeling when he supported S. 1552 as amended by the Committee, and he went on to say that "doctors would be able to see more readily the generic name of drugs, if they are in larger type." 108 Cong. Rec. 17369 (1962).[18]

[18]In this connection, it must be emphasized that the statutory requirement is applicable only to prescription drugs, and that labels, labeling, and advertising matter for these drugs are directed to

The point here is that there was no mention in any of these statements of an "every time" requirement—the purpose was simply to prevent nondisclosure of the established name. Nor did the two other Senators who spoke on the established name provision during the Senate Floor debate mention an "every time" requirement. See 108 Cong. Rec. 17366-67 (1962) (remarks of Senator East[illegible]); *id.* at 17383 (remarks of Senator Hart). Similarly, there was no reference to an "every time" requirement during the House debate.

In short, the legislative history reveals, [illegible] the District Court (R. 53-54), that Congress [illegible]erned about nondisclosure of established name[illegible] they were disclosed, the small type in which they [illegible]nted. Congress chose an appropriate remedy by requiring that the established name appear conspicuously on labels, labeling, and advertisements—*i.e.*, that it appear "prominently and in type at least half as large as that used for any" proprietary name. Congress did no more than this. There is nothing to indicate congressional concern over the frequency of appearance of the established name, and nothing to indicate that Congress intended an "every time" requirement.

CONCLUSION

The judgments of the Court of Appeals should be reversed. The case should be remanded to the Court of Appeals for a determination of the merits. If, however, this

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physicians and not to the general public. (R. 8). In the absence of legislative history to the contrary, it can hardly be assumed that Congress believed that physicians, who are highly trained and knowledgeable in this area, would require an "every time" repetition of a drug's established name in order to become aware of that name. While constant repetition may be desirable for children learning the multiplication tables, it is wholly inappropriate and unnecessary for physicians, and can easily be distracting and annoying to any careful reader. (R. 14-15.)

Court should determine the merits, the judgment of the District Court (except as to its venue ruling) should be affirmed.

Respectfully submitted,

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SUPREME COURT OF THE UNITED STATES

No. 39.—October Term, 1966.

Abbott Laboratories et al., Petitioners, *v.* John W. Gardner, Secretary of Health, Education, and Welfare, et al.	On Writ of Certiorari to the United States Court of Appeals for the Third Circuit.

[May 22, 1967.]

Mr. Justice Harlan delivered the opinion of the Court.

In 1962 Congress amended the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. § 301 *et seq.*, to require manufacturers of prescription drugs to print the "established name" of the drug "prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug," on labels and other printed material, § 502 (e)(1)(B), 21 U. S. C. § 352 (e)(1)(B). The "established name" is one designated by the Secretary of Health, Education, and Welfare pursuant to § 502 (e)(2) of the Act, 21 U. S. C. § 352 (e)(2); the "proprietary name" is usually a trade name under which a particular drug is marketed. The underlying purpose of the 1962 Amendment was to bring to the attention of doctors and patients the fact that many of the drugs sold under familiar trade names are actually identical to drugs sold under their "established" or less familiar trade names at significantly lower prices. The Commissioner of Food and Drugs, exercising authority delegated to him by the Secretary, 22 Fed. Reg. 1051, 25 Fed. Reg. 8625, published proposed regulations designed to implement the statute, 28 Fed. Reg. 1448. After inviting and considering comments submitted by

interested parties the Commissioner promulgated the following regulation for the "efficient enforcement" of the Act, § 701 (a), 21 U. S. C. § 371 (a):

> "If the label or labeling of a prescription drug bears a proprietary name or designation for the drug or any ingredient thereof, the established name, if such there be, corresponding to such proprietary name or designation, shall accompany each appearance of such proprietary name or designation." 21 CFR 1.104 (g)(1).

A similar rule was made applicable to advertisements for prescription drugs, 21 CFR 1.105 (b)(1).

The present action was brought by a group of 37 individual drug manufacturers and by the Pharmaceutical Manufacturers Association, of which all the plaintiff companies are members, and which includes manufacturers of more than 90% of the Nation's supply of prescription drugs. They challenged the regulations on the ground that the Commissioner exceeded his authority under the statute by promulgating an order requiring labels, advertisements, and other printed matter relating to prescription drugs to designate the established name of the particular drug involved every time its trade name is used anywhere in such material.

The District Court, on cross motions for summary judgment, granted the declaratory and injunctive relief sought, finding that the statute did not sweep so broadly as to permit the Commissioner's "every time" interpretation. 228 F. Supp. 855. The Court of Appeals for the Third Circuit reversed without reaching the merits of the case. 352 F. 2d 286. It held first that under the statutory scheme provided by the Federal Food, Drug, and Cosmetic Act pre-enforcement [1] review of these regu-

[1] That is, a suit brought by one before any attempted enforcement of the statute or regulation against him.

lations was unauthorized and therefore beyond the jurisdiction of the District Court. Second, the Court of Appeals held that no "actual case or controversy" existed and, for that reason, that no relief under the Administrative Procedure Act, 5 U. S. C. §§ 701–704 (recodified in Pub. Law 89–554, 80 Stat. 378), or under the Declaratory Judgment Act, 28 U. S. C. § 2201, was in any event available. Because of the general importance of the question, and the apparent conflict with the decision of the Court of Appeals for the Second Circuit in *Toilet Goods Assn.* v. *Gardiner*, 360 F. 2d 677, which we also review today, *post*, p. —, we granted certiorari. 383 U. S. 924.

I.

The first question we consider is whether Congress by the Federal Food, Drug, and Cosmetic Act intended to forbid pre-enforcement review of this sort of regulation promulgated by the Commissioner. The question is phrased in terms of "prohibition" rather than "authorization" because a survey of our cases shows that judicial review of a final agency action by an aggrieved person will not be cut off unless there is persuasive reason to believe that such was the purpose of Congress. *Board of Governors* v. *Agnew*, 329 U. S. 441; *Heikkila* v. *Barber*, 345 U. S. 229; *Brownell* v. *Tom We Shung*, 352 U. S. 180; *Harmon* v. *Brucker*, 355 U. S. 579; *Leedom* v. *Kyne*, 358 U. S. 184; *Rusk* v. *Cort*, 369 U. S. 367. Early cases in which this type of judicial review was entertained, *e. g.*, *Shields* v. *Utah Idaho Central R. R.*, 305 U. S. 177; *Stark* v. *Wickard*, 321 U. S. 288, have been reinforced by the enactment of the Administrative Procedure Act, which embodies the basic presumption of judicial review to one "suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute," 5 U. S. C. § 702, so long as no statute precludes such

relief or the action is not one committed by law to agency discretion, 5 U. S. C. § 701 (a). The Administrative Procedure Act provides specifically not only for review of "Agency action made reviewable by statute" but also for review of "final agency action for which there is no other adequate remedy in a court," 5 U. S. C. § 704. The legislative material elucidating that seminal act manifests a congressional intention that it cover a broad spectrum of administrative actions,[3] and this Court has echoed that theme by noting that the Administrative Procedure Act's "generous review provisions" must be given a "hospitable" interpretation. *Shaughnessy* v. *Pedreiro*, 349 U. S. 48, 51; see *United States* v. *Interstate Commerce Comm'n*, 337 U. S. 426, 433–435; *Brownell* v. *Tom We Shung*, *supra*; *Heikkila* v. *Barber*, *supra*. Again in *Rusk* v. *Cort*, *supra*, at 379–380, the Court held that only upon a showing of "clear and convincing evidence" of a contrary legislative intent should the courts restrict access to judicial review. See also Jaffe, Judicial Control of Administrative Action 336–359 (1965).

Given this standard, we are wholly unpersuaded that the statutory scheme in the food and drug area excludes this type of action. The Government relies on no explicit statutory authority for its argument that pre-enforcement review is unavailable, but insists instead that because the statute includes a specific procedure for such review of certain enumerated kinds of regulations,[4] not encompass-

[3] See H. R. Rep. No. 1980, 79th Cong., 2d Sess., 41 (1946): "To preclude judicial review under this bill a statute, if not specific in withholding such review, must upon its face give clear and convincing evidence of an intent to withhold it. The mere failure to provide specially by statute for judicial review is certainly no evidence of intent to withhold review." See also S. Rep. No. 752, 79th Cong., 1st Sess., 26 (1946).

[4] Embodied in §§ 701 (e), (f), 21 U. S. C. §§ 371 (e), (f), and discussed hereafter. Section 701 (e) provides a procedure for the

ing those of the kind involved here, other types were necessarily meant to be excluded from any pre-enforcement review. The issue, however, is not so readily resolved; we must go further and inquire whether in the context of the entire legislative scheme the existence of that circumscribed remedy evinces a congressional purpose to bar agency action not within its purview from judicial review. As a leading authority in this field has noted, "The mere fact that some acts are made reviewable should not suffice to support an implication of exclusion as to others. The right to review is too important to be excluded on such slender and indeterminate evidence of legislative intent." Jaffe, *supra*, p. 357.

In this case the Government has not demonstrated such a purpose; indeed, a study of the legislative history shows rather conclusively that the specific review provisions were designed to give an additional remedy and not to cut down more traditional channels of review. At the time the Food, Drug, and Cosmetic Act was under consideration, in the late 1930's, the Administrative Procedure Act had not yet been enacted,[4] the Declaratory Judgment Act was in its infancy,[5] and the scope of judicial review of administrative decisions under the equity power was unclear.[6] It was these factors that led to the form the statute ultimately took. There is no evidence at all that members of Congress meant to preclude traditional avenues of judicial relief. Indeed, throughout the consideration of the various bills submitted to deal with this issue,

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issuance of regulations under certain specifically enumerated statutory sections. Section 701 (f) establishes a procedure for direct review by a court of appeals of a regulation promulgated under § 701 (e).

[4] The Administrative Procedure Act was enacted in 1946, 60 Stat. 237.

[5] The Declaratory Judgment Act was enacted in 1934, 48 Stat. 955.

[6] See, *e. g.*, the discussion of judicial review under the equity power in the House of Representatives during the debate on these provisions. 83 Cong. Rec. 7891–7896 (1938).

it was recognised that "There is always an appropriate remedy in equity in cases where an administrative officer has exceeded his authority and there is no adequate remedy of law, . . . [and that] protection is given by the so-called Declaratory Judgment Act. . . ." H. R. Rep. No. 2755, 74th Cong., 2d Sess., 8. It was specifically brought to the attention of Congress that such methods had in fact been used in the food and drug area,[7] and the Department of Justice, in opposing the enactment of the special review procedures of § 701, submitted a memorandum which was read on the floor of the House stating: "As a matter of fact, the entire subsection is really unnecessary, because even without any express provision in the bill for court review, any citizen aggrieved by any order of the Secretary, who contends that the order is invalid, may test the legality of the order by bringing an injunction suit against the Secretary, or the head of the Bureau, under the general equity powers of the court." 83 Cong. Rec. 7892 (1938).

The main issue in contention was whether these methods of review were satisfactory. Compare the majority and minority reports on the review provisions, H. R. Rep. No. 2139, 75th Cong., 3d Sess. (1938), both of which acknowledged that traditional judicial remedies were available, but disagreed as to the need for additional procedures. The provisions now embodied in a modified form in § 701 (f) were supported by those who feared the life-and-death power given by the Act to the executive officials, a fear voiced by many members of Congress. The supporters of the special review section sought to include it in the Act primarily as a method of reviewing

[7] See, *e. g.*, 83 Cong. Rec. 7783 (remarks of Representative Leavy) (1938); Statement of Professor David F. Cavers before a Subcommittee of the Senate Committee on Commerce on S. 1944, 73d Cong., 2d Sess. (1933), reprinted in Dunn, Federal Food, Drug, and Cosmetic Act: A Statement of Its Legislative Record 1110 (1938).

agency *factual* determinations. For example, it was argued that the level of tolerance for poisonous sprays on apple crops, which the Secretary of Agriculture had recently set, was a factual matter, not reviewable in equity in the absence of a special statutory review procedure.[8] Some congressmen urged that challenge to this type of determination should be in the form of a *de novo* hearing in a district court, but the Act as it was finally passed compromised the matter by allowing an appeal on a record with a "substantial evidence" test, affording a considerably more generous judicial review than the "arbitrary and capricious" test available in the traditional injunctive suit.[9]

A second reason for the special procedure was to provide broader venue to litigants challenging such technical agency determinations. At that time, a suit against the Secretary was proper only in the District of Columbia, an advantage that the Government sought to preserve. The House bill, however, originally authorized review in any district court, but in the face of a Senate bill allowing review only in the District of Columbia, the Conference Committee reached the compromise preserved in the present statute authorizing review of such agency actions by the courts of appeals.[10]

Against this background we think it quite apparent that the special review procedures provided in § 701 (f), applying to regulations embodying technical factual determinations,[11] were simply intended to assure adequate

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[8] See, *e. g.*, 83 Cong. Rec. 7772–7773, 7781–7784, 7893–7899 (1938).

[9] See, *e. g.*, the discussion of the conference report, 83 Cong. Rec. 9096–9098 (1938).

[10] See, *e. g.*, 83 Cong. Rec. 7772, 7892, 9092–9093 (1938).

[11] See *Toilet Goods Assn. v. Gardiner*, 380 F. 2d 677, 683, where the court noted that "The agency determinations specifically reviewable under § 701 (e) relate to such technical subjects as chemical properties of particular products and the formulation and applica-

judicial review of such agency decisions, and that their enactment does not manifest a congressional purpose to eliminate judicial review of other kinds of agency action.

This conclusion is strongly buttressed by the fact that the Act itself, in § 701 (f)(6), states, "The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law." This savings clause was passed over by the Court of Appeals without discussion. In our view, however, it bears heavily on the issue, for if taken at face value it would foreclose the Government's main argument in this case. The Government deals with the clause by arguing that it should be read as applying only to review of regulations under the sections specifically enumerated in § 701 (e). This is a conceivable reading, but it requires a considerable straining both of language and of common understanding. The savings clause itself contains no limitations, and it requires an artificial statutory construction to read a general grant of a right to judicial review begrudgingly, so as to cut out agency actions that a literal reading would cover.

There is no support in the legislative background for such a reading of the clause. It was included in the House bill, whose report states that the provision ". . . saved as a method to review a regulation placed in effect by the Secretary whatever rights exist to initiate a historical proceeding in equity to enjoin the enforcement of the regulation, and whatever rights exist to initiate a declaratory judgment proceeding." H. R. Rep. No. 2139, 75th Cong., 3d Sess., 11. The Senate conferees accepted the provision.[12] The Government argues

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tion of safety standards for protecting public health; Congress naturally did not wish courts to consider such matters without the benefit of the agency's views after an evidentiary hearing before it."

[12] H. R. Rep. No. 2716, 75th Cong., 3d Sess., 25 (1938) (conference report); 83 Cong. Rec. 8731–8738 (1938) (Senate agreement to the conference report).

that the clause is included as a part of § 701 (f), and therefore should be read to apply only to those sections to which the § 701 (f) special-review procedure applies. But it is difficult to think of a more appropriate place to put a general savings clause than where Congress placed it—at the conclusion of the section setting out a special procedure for use in certain specified instances. Furthermore, the Government's reading would result in an anomaly. The § 701 (e)(f) procedure was included in the Act in order to deal with the problem of technical determinations for which the normal equity power was deemed insufficient. See, *supra*, pp. —, —. There would seem little reason for Congress to have enacted § 101 (f), and at the same time to have included a clause aimed only at preserving for such determinations the other types of review whose supposed inadequacy was the very reason for the special-review provisions.

Under the Government's view, indeed, it is difficult to ascertain when the savings clause would even come into play: when the special provisions apply, presumably they must be used and a court would not grant injunctive or declaratory judgment relief unless the appropriate administrative procedure is exhausted.[13] When the special procedure does not apply, the Government deems the savings clause likewise inapplicable. The Government, to be sure, does present a rather far-fetched example of what it considers a possible application of the relief saved by § 701 (f)(6), but merely to state it reveals the weakness of the Government's position.[14] We prefer to take the

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[13] See Notes of the Advisory Committee on Federal Rule of Civil Procedure 57, reprinted in 28 U. S. C. App., p. 6136 (1964 ed.): "A declaration may not be rendered if a special statutory proceeding has been provided for the adjudication of some special type of case . . . ." See also 6 Moore, Federal Practice § 57.08[3] (1966 ed.).

[14] The Government apparently views the clause as applying only when regulations falling within the special review procedure are promulgated without affording the required public notice and oppor-

savings clause at its face value, and to read it in harmony with the policy favoring judicial review expressed in the Administrative Procedure Act and this Court's decisions.

The only other argument of the Government requiring attention on the preclusive effect of the statute is that *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U. S. 594, counsels a restrictive view of judicial review in the food and drug area. In that case the Food and Drug Administrator found that there was probable cause that a drug was "adulterated" because it was misbranded in such a way as to be "fraudulent" or "misleading to the injury or damage of the purchaser or consumer." § 304 (a), 21 U. S. C. § 334 (a). Multiple seizures were ordered through libel actions. The manufacturer of the drug brought an action to challenge directly the Administrator's finding of probable cause. This Court held that the owner could raise his constitutional, statutory, and factual claims in the libel actions themselves, and that the mere finding of probable cause by the Administrator could not be challenged in a separate action. That decision was quite clearly correct, but nothing in its reasoning or holding has any bearing on this declaratory judgment action challenging a promulgated regulation.

The Court in *Ewing* first noted that the "administrative finding of probable cause required by § 304 (a) is merely the statutory prerequisite to the bringing of the lawsuit," at which the issues are aired. 339 U. S., at 598. Such a situation bears no analogy to the promulgation, after formal procedures, of a rule that must be followed by an entire industry. To equate a finding of probable cause for proceeding against a particular drug

tunity to file objections and to request a public hearing. In such a case alone, the Government asserts, "an equity proceeding or a declaratory judgment action . . . might be entertained on the ground that the statutory procedures had not been followed." Brief, p. 28.

manufacturer with the promulgation of a self-operative industry-wide regulation, such as we have here, would immunize nearly all agency rulemaking activities from the coverage of the Administrative Procedure Act.

Second, the determination of probable cause in *Ewing* has "no effect in and of itself," 339 U. S., at 598; only some action consequent upon such a finding could give it legal life. As the Court there noted, like a determination by a grand jury that there is probable cause to proceed against an accused, it is a finding which only has vitality once a proceeding is commenced, at which time appropriate challenges can be made. The Court also noted that the unique type of relief sought by the drug manufacturer was inconsistent with the policy of the Act favoring speedy action against goods in circulation that are believed on probable cause to be adulterated. Also, such relief was not specifically granted by the Act, which did provide another type of relief in the form of a consolidation of multiple libel actions in a convenient venue. 339 U. S., at 602.

The drug manufacturer in *Ewing* was quite obviously seeking an unheard of form of relief which, if allowed, would have permitted interference in the early stages of an administrative determination as to specific facts, and would have prevented the regular operation of the seizure procedures established by the Act. That the Court refused to permit such an action is hardly authority for cutting off the well-established jurisdiction of the federal courts to hear, in appropriate cases, suits under the Declaratory Judgment Act and the Administrative Procedure Act challenging final agency action of the kind present here.

We conclude that nothing in the Food, Drug, and Cosmetic Act itself precludes this action.

II.

A further inquiry must, however, be made. The injunctive and declaratory judgment remedies are discretionary, and courts traditionally have been reluctant to apply them to administrative determinations unless these arise in the context of a controversy "ripe" for judicial resolution. Without undertaking to survey the intricacies of the ripeness doctrine[15] it is fair to say that its basic rationale is to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties. The problem is best seen in a two fold aspect, requiring us to evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.

As to the former factor, we believe the issues presented are appropriate for judicial resolution at this time. First, all parties agree that the issue tendered is a purely legal one: whether the statute was properly construed by the Commissioner to require the established name of the drug to be used *every time* the proprietary name is employed.[16] Both sides moved for summary judgment in the District Court, and no claim is made here that further administrative proceedings are contemplated. It is suggested that the justification for this rule might vary with different circumstances, and that the expertise of the Commis-

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[15] See 3 Davis, Administrative Law Treatise, c. 21 (1958); Jaffe, Judicial Control of Administrative Action, c. 10 (1965).

[16] While the "every time" issue has been framed by the parties in terms of statutory *compulsion*, we think that its essentially legal character would not be different had it been framed in terms of statutory *authorization* for the requirement.

sioner is relevant to passing upon the validity of the regulation. This of course is true, but the suggestion overlooks the fact that both sides have approached this case as one purely of congressional intent, and that the Government made no effort to justify the regulation in factual terms.

Second, the regulations in issue we find to be "final agency action" within the meaning of § 10 of the Administrative Procedure Act, 5 U. S. C. § 704, as construed in judicial decisions. An "agency action" includes any "rule," defined by the Act as "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy," §§ 2 (c), (g), 5 U. S. C. §§ 551 (4), (13). The cases dealing with judicial review of administrative actions have interpreted the "finality" element in a pragmatic way. Thus in *Columbia Broadcasting System* v. *United States*, 316 U. S. 407, a suit under the Urgent Deficiencies Act, 38 Stat. 219, this Court held reviewable a regulation of the Federal Communications Commission setting forth certain proscribed contractual arrangements between chain broadcasters and local stations. The FCC did not have direct authority to regulate these contracts, and its rule asserted only that it would not license stations which maintained such contracts with the networks. Although no license had in fact been denied or revoked, and the FCC regulation could properly be characterized as a statement only of its intentions, the Court held that "Such regulations have the force of law before their sanctions are invoked as well as after. When, as here, they are promulgated by order of the Commission and the expected conformity to them causes injury cognizable by a court of equity, they are appropriately the subject of attack . . . ." 316 U. S., at 418–419.

Two more recent cases have taken a similarly flexible view of finality. In *Frozen Food Express* v. *United States*, 351 U. S. 40, at issue was an Interstate Commerce Commission order specifying commodities that were deemed to fall within the statutory class of "agricultural commodities." Vehicles carrying such commodities were exempt from ICC supervision. An action was brought by a carrier that claimed to be transporting exempt commodities, but which the ICC order had not included in its terms. Although the dissenting opinion noted that this ICC order had no authority except to give notice of how the Commission interpreted the Act and would have effect only if and when a particular action was brought against a particular carrier, and argued that "judicial intervention [should] be withheld until administrative action has reached its complete development," 351 U. S., at 45, the Court held the order reviewable.

Again, in *United States* v. *Storer Broadcasting Co.*, 351 U. S. 192, the Court held to be a final agency action within the meaning of the Administrative Procedure Act an FCC regulation announcing a Commission policy that it would not issue a television license to an applicant already owning five such licenses, even though no specific application was before the Commission. The Court stated: "The process of rulemaking was complete. It was final agency action . . . by which Storer claimed to be 'aggrieved.'" 351 U. S., at 198.

We find decision in the present case following *a fortiori* from these precedents. The regulation challenged here, promulgated in a formal manner after announcement in the Federal Register and consideration of comments by interested parties[17] is quite clearly definitive. There is

[17] Compare similar procedures followed in *Frozen Food Express*, *supra*, at 41–42, and *Storer*, *supra*, at 193–194. The procedure conformed with that prescribed in § 4 of the Administrative Procedure Act, 5 U. S. C. § 1003.

no hint that this regulation is informal, see *Helco Products Co.* v. *McNutt*, 137 F. 2d 681, or only the ruling of a subordinate official, see *Swift & Co.* v. *Wickham*, 230 F. Supp. 398, 409, affirmed, 364 F. 2d 241, or tentative. It was made effective upon publication, and the Assistant General Counsel for Food and Drugs stated in the District Court that compliance was expected.

The Government argues, however, that the present case can be distinguished from cases like *Frozen Food Express* on the ground that in those instances the agency involved could implement its policy directly, while here the Attorney General must authorize criminal and seizure actions for violations of the statute. In the context of this case, we do not find this argument persuasive. These regulations are not meant to advise the Attorney General, but purport to be directly authorized by the statute. Thus, if within the Commissioner's authority, they have the status of law and violations of them carry heavy criminal and civil sanctions. Also, there is no representation that the Attorney General and the Commissioner disagree in this area; the Justice Department is defending this very suit. It would be adherence to a mere technicality to give any credence to this contention. Moreover, the agency does have direct authority to enforce this regulation in the context of passing upon applications for clearance of new drugs, § 505, 21 U. S. C. § 355, or certification of certain antibiotics, § 507, 21 U. S. C. § 357.

This is also a case in which the impact of the regulations upon the plaintiffs is sufficiently direct and immediate so as to render the issue appropriate for judicial review at this stage. These regulations purport to give an authoritative interpretation of a statutory provision that has a direct effect on the day-to-day business of all prescription drug companies; its promulgation puts petitioners in a dilemma that it was the very purpose of the

Declaratory Judgment Act to ameliorate.[18] As the District Court found on the basis of uncontested allegations, "Either they must comply with the every time requirement and incur the costs of changing over their promotional material and labeling or they must follow their present course and risk prosecution." 228 F. Supp. 855, 861. The regulations are clear-cut, and were made effective immediately upon publication; as noted earlier the agency's counsel represented to the District Court that immediate compliance with their terms was expected. If petitioners wish to comply they must change all their labels, advertisements, and promotional materials; they must destroy stocks of printed matter; and they must invest heavily in new printing type and new supplies. The alternative to compliance—continued use of material which they believe in good faith meets the statutory requirements, but which clearly does not meet the regulation of the Commissioner—may be even more costly. That course would risk serious criminal and civil penalties for the unlawful distribution of "misbranded" drugs.[19]

It is relevant at this juncture to recognize that petitioners deal in a sensitive industry, in which public confidence in their drug products is especially important. To require them to challenge these regulations only as a defense to an action brought by the Government might harm them severely and unnecessarily. Where the legal issue presented is fit for judicial resolution, and where a regulation requires an immediate and significant change

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[18] See S. Rep. No. 1005, 73d Cong., 2d Sess., 2–3 (1934); Borchard, Challenging "Penal" Statutes by Declaratory Action, 52 Yale L. J. 445, 454 (1943).

[19] Section 502 (e)(1)(B) declares a drug not complying with this labeling requirement to be "misbranded." Section 301, 21 U. S. C. § 331, designates as "prohibited acts" the misbranding of drugs in interstate commerce. Such prohibited acts are subject to injunction, § 302, 21 U. S. C. § 332, criminal penalties, § 303, 21 U. S. C. § 333, and seizure, § 304 (a), 21 U. S. C. § 334 (a).

in the plaintiffs' conduct of their affairs with serious penalties attached to noncompliance, access to the courts under the Administrative Procedure Act and the Declaratory Judgment Act must be permitted, absent a statutory bar or other unusual circumstances, neither of which appears here.

The Government does not dispute the very real dilemma in which petitioners are placed by the regulation, but contends that "mere financial expense" is not a justification for pre-enforcement judicial review. It is of course true that cases in this Court dealing with the standing of particular parties to bring an action have held that a possible financial loss is not by itself a sufficient interest to sustain a judicial challenge to governmental action. *Frothingham* v. *Mellon*, 262 U. S. 447; *Perkins* v. *Lukens Steel Co.*, 310 U. S. 113. But there is no question in the present case that petitioners have sufficient standing as plaintiffs: the regulation is directed at them in particular; it requires them to make significant changes in their everyday business practices; if they fail to observe the Commissioner's rule they are quite clearly exposed to the imposition of strong sanctions. Compare *Columbia Broadcasting System, Inc.* v. *United States*, 316 U. S. 407; 3 Davis, Administrative Law Treatise, c. 21 (1958). This case is, therefore, remote from the *Mellon* and *Perkins* cases.

The Government further contends that the threat of criminal sanctions for noncompliance with a judicially untested regulation is unrealistic; the Solicitor General has represented that if court enforcement becomes necessary, "the Department of Justice will proceed only civilly for an injunction . . . or by condemnation." We cannot accept this argument as a sufficient answer to petitioners' petition. This action at its inception was properly brought and this subsequent representation of the Department of Justice should not suffice to defeat it.

Finally the Government urges that to permit resort to the courts in this type of case may delay or impede

effective enforcement of the Act. We fully recognize the important public interest served by assuring prompt and unimpeded administration of the Pure Food, Drug, and Cosmetic Act, but we do not find the Government's argument convincing. First, in this particular case, a pre-enforcement challenge by nearly all prescription drug manufacturers is calculated to speed enforcement. If the Government prevails, a large part of the industry is bound by the decree; if the Government loses, it can more quickly revise its regulation.

The Government contends, however, that if the Court allows this consolidated suit, then nothing will prevent a multiplicity of suits in various jurisdictions challenging other regulations. The short answer to this contention is that the courts are well equipped to deal with such eventualities. The venue transfer provision, 28 U. S. C. § 1404 (a), may be invoked by the Government to consolidate separate actions. Or, actions in all but one jurisdiction might be stayed pending the conclusion of one proceeding. See *American Life Ins. Co.* v. *Stewart*, 300 U. S. 203, 215–216. A court may even in its discretion dismiss a declaratory judgment or injunctive suit if the same issue is pending in litigation elsewhere. *Maryland Cas. Co.* v. *Consumers Finance Serv.*, 101 F. 2d 514; *Carbide & Carbon C. Corp.* v. *United States I. Chems.*, 140 F. 2d 47; Note, Availability of a Declaratory Judgment When Another Suit Is Pending, 51 Yale L. J. 511 (1942). In at least one suit for a declaratory judgment, relief was denied with the suggestion that the plaintiff intervene in a pending action elsewhere. *Automotive Equip., Inc.* v. *Trico Prods. Corp.*, 11 F. Supp. 292; See *Allstate Ins. Co.* v. *Thompson*, 121 F. Supp. 696.

Further, the declaratory judgment and injunctive remedies are equitable in nature, and other equitable defenses may be interposed. If a multiplicity of suits are undertaken in order to harass the Government or to delay enforcement, relief can be denied on this ground alone. *Truly* v. *Wanzer*, 5 How. 141, 142; cf. *Brillhart* v. *Excess*

Ins. Co., 316 U. S. 491, 495. The defense of laches could be asserted if the Government is prejudiced by a delay, *Southern Pac. Co.* v. *Bogert*, 250 U. S. 483, 488–490; 2 Pomeroy's Equity Jurisprudence §§ 419c, d (5th ed. Symons, 1941). And courts may even refuse declaratory relief for the nonjoinder of interested parties who are not, technically speaking, indispensable. Cf. *Samuel Goldwyn, Inc.* v. *United Artists Corp.*, 113 F. 2d 703; 6 Moore, Federal Practice ¶ 57.25.

In addition to all these safeguards against what the Government fears, it is important to note that the institution of this type of action does not by itself stay the effectiveness of the challenged regulation. There is nothing in the record to indicate that petitioners have sought to stay enforcement of the "every time" regulation pending judicial review. See 5 U. S. C. § 705. If the agency believes that a suit of this type will significantly impede enforcement or will harm the public interest, it need not postpone enforcement of the regulation and may oppose any motion for a judicial stay on the part of those challenging the regulation. *Ibid.* It is scarcely to be doubted that a court would refuse to postpone the effective date of an agency action if the Government could show, as it made no effort to do here, that delay would be detrimental to the public health or safety. See *Associated Securities Corp.* v. *SEC*, 283 F. 2d 773, 775, where a stay was denied because "the petitioners . . . [had] not sustained the burden of establishing that the requested stay will not be harmful to the public interest . . ."; see *Eastern Air Lines* v. *CAB*, 261 F. 2d 830; cf. *Scripps-Howard Radio* v. *FCC*, 316 U. S. 4, 10–11; 5 U. S. C. § 705.

Lastly, although the Government presses us to reach the merits of the challenge to the regulation in the event we find the District Court properly entertained this action, we believe the better practice is to remand the case to the Court of Appeals for the Third Circuit to review

the District Court's decision that the regulation was beyond the power of the Commissioner.[20]

Reversed and remanded.

MR. JUSTICE BRENNAN took no part in the consideration or decision of this case.

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[20] A totally separate issue raised in the petition for certiorari and argued by the parties in their briefs concerns the dismissal of the complaint as to certain of the plaintiffs on the ground that venue was improper as to them. All the petitioners asserted that venue was proper in Delaware not only because some of them are incorporated there but also under 28 U. S. C. § 1391 (e)(4), allowing an action against a government official in any judicial district in which "the plaintiff resides . . . ." It is contended that § 1391 (e)(4) must be read to incorporate the definition of "residence" set out in 28 U. S. C. § 1391 (c): "A corporation may be sued in any judicial district in which it is incorporated or licensed to do business or is doing business, and such judicial district shall be regarded as the residence of such corporation for venue purposes." The issue of construction is whether § 1391 (c) should be read as defining corporate venue only when the corporation is a defendant, or whether it should either (1) be adopted for corporate residence in all cases when a corporation is a plaintiff, or (2) at least as the definition of "resides" as used in § 1391 (e)(4).

This question is a difficult one, with far-reaching effects, and we think it is appropriate to dismiss our writ of certiorari as to this question for the following two reasons. First, the Court of Appeals in affirming the District Court on this issue did not explicitly endorse the lower court's ruling but held only: "We find no prejudicial error in the dismissal of the complaint as to these plaintiffs . . . ." 352 F. 2d 524, 525. Review of an issue of this importance is best left to a case where it has been fully dealt with by a court of appeals. Second, one of the plaintiffs whose complaint was not dismissed is the Pharmaceutical Manufacturers Association, of which all the corporate petitioners are members, and we think it should be considered that they are adequately protected in this suit by its participation, as well as by the participation of the remaining drug companies whose interests are identical to those of the petitioners whose complaints were dismissed. Cf. *Miahlin* v. *New York*, 383 U. S. 502, 512–514. Moreover, in the further course of this litigation it will be open to the dismissed plaintiffs to seek *amicus curiae* status.